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The Journal of the Connecticut State Medical Society

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scientific:

. Polednak 3 **Do Physicians Discuss Genetic Testing with Family-history-positive Breast Cancer Patients?**
yn A. Quin, t Thomson, J. Dudrick 9 **Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Review of the Connecticut State Tumor Registry**
Neumann, rt J. Scholl 15 **ACase Report: Extralobar Pulmonary Sequestration in a Newborn**
Epitomes of Progress
ljeet S. Rai 19 **Important Advances in Clinical Medicine—Family and General Practice**
Drug Information Update: Hartford Hospital
l Jack Ross 25 **Antiretroviral Therapy: An Update**
Morbidity and Mortality Weekly Report
29 **Outbreak of Staphylococcal Food Poisoning, Associated with Precooked Ham—Florida, 1997**
The Medical Letter
31 **St. John's Wort**

articles:

l J. Galena, Charles R. Epstein, and Rita J. Lourie 33 **Connecticut State Special Olympics: Observations and Recommendations**
Maria Lenaz 39 **Research Promotion Between Managed Care Organizations and Healthcare Delivery Sytems**
Harry Yoon 41 **Two Lives, Interlaced, End One Day Apart**

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Fifty Years Ago
43 **Fifth Memorial Gift to Building Fund**
The President's Page
Stanley J. Keating, Jr. 45 **Preaching to the Choir**
Reflections on Medicine
Robert U. Massey 47 **The Kinsey Report: After 50 Years, Bogus Science**
Medical News Capsules
Timothy B. Norbeck 49 **This Month's Reading in Review**
Letters to the Editor
Arnold A. Heiger 50 **Round Table Discussion**
Stephen T. Sinatra 50 **In Response to *Thiamine Deficiency* Article**
Stephen R. Katz 50 **In Response to Dr. Lenaz's Letter "Ethics in Managed Care"**
Timothy C. Merrick 51 **In Response to Dr. Chotkowski's Letter**
L.A. Chotkowski 52 **Dr. Chotkowski Responds to Dr. Merrick**
Robert J. Brunell 53 **Obituary—Robert R. McDonnell**

general:

55 **In Memoriam**
57 **CSMS Physician Placement Service**

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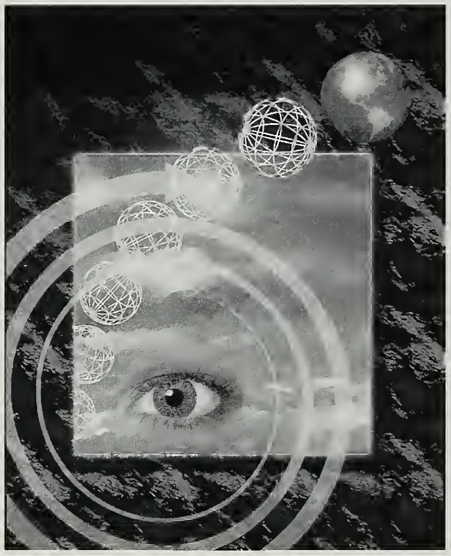

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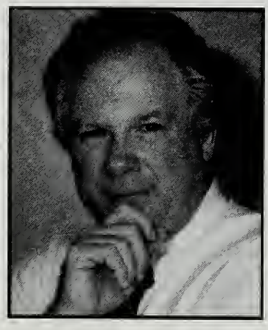

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Do Physicians Discuss Genetic Testing with Family-history-positive Breast Cancer Patients?

ANTHONY P. POLEDNAK

ABSTRACT—Genetic testing for carriers of known germ-cell mutations involved in hereditary breast cancer in families should start with affected family members, in order to avoid ambiguous test results in unaffected members. A survey was conducted (May to August 1997) of physicians involved in the follow-up care of family-history-positive breast cancer patients diagnosed in 1994 and 1995, identified in the Connecticut Tumor Registry. Only 14 (18%) of 76 responding physicians reported having received an advertisement about commercially available tests for genes involved in inherited breast cancer, and only 12 (16%) reported discussing genetic testing with a patient included in this study. None of the 74 patients involved were known (by the responding physicians) to have been tested. However, further surveys are needed because awareness of the availability of genetic tests may be growing.

DESPITE the rapid pace of discovery of genes involved in inherited susceptibility to cancer, none of the genetic tests are generally regarded by geneticists and patient advocates as appropriate for screening the general population,[1,2] although this is a subject of ongoing debate.[3] By early 1996, however, several biotechnology companies were marketing (to health-care providers) genetic tests for germ-line mutations in a tumor-suppressor gene (BRCA1) involved in "inherited" breast and ovarian cancers; Myriad Genetics began testing for both BRCA1 and BRCA2 in November 1996.[1,3] Some of these companies, and some clinics, require a family history of the disease as a prerequisite for testing, while others do not.[1,3]

The identification of a mutation known to be involved in breast or breast/ovarian cancer in an affected member of a family can be used as a "critical baseline" in the testing of other family members.[2] Thus, the proper strategy for testing for mutations in known cancer genes in families is first to test an affected family member before testing unaffected relatives. This conclusion is also supported by recent studies showing that only a small proportion of "hereditary" breast cancers involve BRCA1 or BRCA2 gene mutations, especially in families with only breast (and no ovarian) cancers;[1,3] that is, genes other than BRCA1 and 2 must be involved in inherited susceptibility to breast/ovarian cancer. Testing for BRCA1/2 gene mutations in families that include carriers of mutations in genes other than BRCA1/2 can result in false negative results.[4,7] False negative tests also can occur as a result of laboratory error (especially if mutations are not independently verified in a second laboratory prior to patient disclosure) and mutations that are undetectable by any commercially available test, while ambiguous test results involve identified mutations of unknown clinical significance.[2,4] Because only a small proportion of all breast cancers involve inherited susceptibility, negative genetic test results can generate a false sense of security: this emphasizes the need for genetic counseling.[3]

The need for education of physicians regarding genetics and genetic counseling is evident from surveys[8] and has been noted by the Federal Task Force on Genetic Testing (in May 1997).[9] For the adenomatous polyposis coli (APC) gene, where genetic tests can identify the responsible mutation in about 80% of families, one study

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ANTHONY P. POLEDNAK, PH.D., Epidemiologist, Connecticut Tumor Registry, Department of Public Health. Thanks are due to all of the Connecticut physicians who responded (without financial compensation) to the mail questionnaire used in this study.

showed that many physicians did not recognize that a negative genetic test can rule out the disorder in a person at risk for APC only when a mutation has been identified in an affected family member.[10]

Women diagnosed with breast and/or ovarian cancer who also have a family history of one or both of these cancers may be "among the first to be offered testing."[11] This study identified a group of breast cancer patients in Connecticut with a family history of breast cancer and surveyed physicians involved in their follow-up care in order to assess whether or not genetic testing had been discussed with these women.

Materials and Methods

The initial sample for this study included all 101 patients (mean age 59 years, range 35 to 88 years) diagnosed with breast cancer in 1994 or 1995 who were not known to have died and were coded in the population-based Connecticut Tumor Registry (CTR) as having a family history of breast cancer in two or more relatives. However, while the CTR has attempted to collect information on family history of cancer since 1973,[12] family history was missing for 48% of invasive breast cancers diagnosed in 1994–95. Although having two or more relatives with breast cancer was used to define "family-history-positive" patients, even in families with three or more relatives affected by breast/ovarian cancer, germ-line mutations in BRCA1 may be infrequent,[5] and some commercial tests have involved only BRCA1 (and not BRCA2).

Although only one physician responsible for patient follow-up is coded in the computerized CTR database, several may be indicated in CTR hard-copy records for some patients. For patients diagnosed in 1994, two physicians were included in the original sample for some patients; however, responses for the two physicians involved with the same patient were found to be similar. Therefore, for patients diagnosed in 1995, the questionnaire was sent only to the physician of follow-up coded in the CTR computerized database. A mail questionnaire was sent (May–June 1997) to 98 physicians involved in the follow-up of the 101 patients. An address for each physician was obtained from *Folio's Medical Directory* (1997 edition).[13] A second mailing was sent (July–August 1997) to nonresponding physicians.

The one-page questionnaire asked the physician about the patient's vital status and the date the patient was last seen, if a discussion of gene testing had been initiated with the patient, and if the patient had been tested for breast/ovarian cancer gene(s). The result of any genetic testing was not asked, because of anticipated physician concerns about confidentiality, although all CTR records are confidential and (under Connecticut public health regulations) can be used only for medical or scientific research. Physicians were asked if they had received an advertisement(s) regarding commercial tests for breast/ovarian cancer gene(s), and the name of the commercial company (OncorMed, Myriad Genetics, or other). Family history of breast/ovarian cancer was asked, including the relationship to the patient and age at diagnosis of (and/or death from) breast or ovarian cancer, in order to assess the potential impact of family history on physicians' decisions about discussing genetic testing with the patient. The study protocol was approved by the Connecticut Department of Public Health's Human Investigations Committee.

Statistical analyses involved calculation of 95% confidence intervals on proportions (using the Normal approximation), a χ^2 test of differences between two proportions, and a t-test (two-tailed) of differences between two means.

Results

A questionnaire, at least partially completed, was returned by 77 of the 98 physicians (79%), covering 74 of 101 patients (73%). Seven other physicians claimed not be to responsible for the follow-up of the patient, one returned a blank questionnaire because the patient had died, one envelope was returned without a forwarding address, and one with only a home address; the remainder did not respond. The majority of physician respondents were surgeons (58%); the remainder of specialties were oncology (with or without internal medicine) (9%), internal medicine (8%), therapeutic radiology/radiation oncology (12%), obstetrics/gynecology (7%), family practice (5%), and unknown (1%).

Each responding physician and each patient were counted only once (Table 1). Only 12 physicians (16%) reported having received an advertisement about commercial tests for breast cancer genes (Table 1). Only 12 physicians (16%) reported discussing genetic testing with the patient (or any of the patients, if more than one) included in the study; one physician refused to answer this question, as well as the question about whether or not the patient had been tested.

Excluding the eight patients last seen prior to 1996 (when genetic tests became commercially available), 11 of 66 patients (16.7%, 95% confidence limits 8.4% and 25%) had a physician or physicians (among those surveyed) who reported ever discussing genetic testing. No patient was identified by the responding physician as having had a genetic test; "don't know" responses (33/74 or 45%) were interpreted as meaning that, to the best of the physician's knowledge, testing had not occurred. Two physicians refused to answer the question about whether or not genetic testing had been done.

Table 1.—Responses of Physicians Involved in the Follow-up of Family-history-positive Breast Cancer Patients Diagnosed in Connecticut in 1994–95

Question	No.	%
Physicians (N=77)		
Ever received advertisement about genetic tests	14	18.2
Myriad Genetics	(10)	(132.0)[†]
OncorMed	(8)	(10.4)[†]
Other	0	0.0
Ever discussed genetic testing with patient included in this study: Yes	12	15.6
No, don't know	63	83.1
Refused to answer	1	1.3
Patients (N=74)[§]		
Year last seen by a physician in this study[◊] 1994, 1995	8	10.8
1996	23	31.1
1997	38	51.4
Not stated	5	6.8
A physician(s) discussed genetic testing[◊]	11	14.9
Ever tested[◊]	0	0.0

[†] More than one commercial testing company was indicated by some physicians.

[§] The number of patients differs from the number of physicians because a questionnaire was sent to two physicians for some patients, but some responding physicians had more than one patient included in the study (see text).

[◊] As reported by a physician in this study.

Of the 12 physicians (for 11 patients) who reported having discussed genetic testing with a patient(s) in the sample (Table 2), five (42%) said that they had received an advertisement about commercially available tests. This proportion was higher (*P*<.01) than the 14% figure for the 64 other physicians. Among these 12 physicians, compared with all other physicians, oncologists were more frequent and year of graduation from medical school prior to 1970 was less frequent (Table 2), although the differences were not statistically significant (*P*>.05) for these small samples. The mean age of the 11 patients (47.5 years) was statistically significantly (*P*=.01, two-tailed t-test) lower than that for the 63 other patients in the study (59.2 years).

Of the 12 physicians who reported discussing genetic testing with a patient included in the study, five (42%) reported that the patient had two relatives who had breast cancer, three (33%) reported one affected relative (25%), and four did not answer (33%). These physician responses for the 11 patients were similar to those of the other 63 patients (ie, 38% had two or more affected relatives, 26% one affected relative, 5% no affected relatives, and 31% had unknown family histories).

Discussion

Limitations of this study include the incomplete ascertainment (in CTR records) of breast cancer patients with a family history of breast cancer. This could affect the representativeness of the patients selected, although cancer registries can be useful for identifying families with multiple cases of a specific cancer(s) for genetic epidemiologic and other studies.[12,14] The low proportion (16%) of physicians who reported having discussed genetic testing could have been underestimated due to nonrespondent bias, although the response rate was higher than the 65% figure in a recent survey of physician knowledge of genetics and genetic tests.[8] No patient was identified as having been tested for breast/ovarian cancer gene(s), although two physicians refused to answer the question and nonrespondent bias could have occurred due to physician concerns about disclosing the fact of genetic testing.

Awareness of a patient's family history of breast cancer differed little between physicians who did (*vs* did not) report discussing genetic testing. Receipt of an advertisement about commercial tests for breast/ovarian gene testing (Table 2) may have influenced the decision of physicians to discuss testing, but this was not assessed directly. Oncologists may be more likely than other specialists to discuss genetic testing (Table 2), because cancer risk counseling is regarded as part of the mission of clinical oncologists,[2] but surveys are needed with larger samples of physicians. The lower proportion of graduates from medical school prior to 1970 among the 12 physicians who

Table 2.—Physicians Who Reported Discussing Genetic Testing with a Patient in the Study: Comparison with All Other Responding Physicians

	Discussed Genetic Testing:			
	Yes (N=12)		No (N=65)	
Variable	No.	%	No.	%
Received advertisement about commercial tests	5	41.7	9	13.8[*]
Medical specialty[†]: Surgery	6	50.0	39	60.0
Radiotherapy	2	16.7	7	10.8
Oncology	3	25.0	4	6.2
Other	1	8.3	15	23.1
Year of graduation from medical school[†]: <1970	2	16.6	23	35.4
1970–79	5	41.7	26	40.0
1980+	4	33.3	14	21.5
Unknown	1	8.3	2	3.1

†From reference 13.
*$P<.05$ for difference between the two groups of physicians; all other differences were statistically insignificant for these sample sizes.

reported discussing genetic testing (Table 2) is noteworthy in view of a report of increasing knowledge of genetics and genetic testing among more recent graduates from medical school (at least among primary-care physicians).[8] Studies are needed with larger samples of physicians involved in the follow-up of breast cancer patients.

This study suggests that physicians are unaware of recent developments in genetic testing for genes involved in inherited breast/ovarian cancer, and/or are cautious about discussing genetic testing with family-history-positive breast cancer patients.[1,3] Physician interest in discussing genetic testing with a breast cancer patient may be strongly influenced not only by the age of the patient (as found in this study) but also by the number of living female relatives (especially daughters) unaffected by breast cancer (which was unknown in this study). When genetic testing is offered, receptivity may be high among unaffected relatives of patients with breast and/or ovarian cancer.[15] However, in hereditary cancer clinics, financial and other barriers to genetic testing may result in low levels of testing in families with multiple cases of breast/ovarian cancer.[16]

Genetic testing of unaffected relatives of breast and ovarian cancer patients raises complex issues regarding potential discrimination by employers and health insurers, misinterpretation of genetic test results by patients and physicians, and uncertainties about appropriate clinical care (such as prophylactic surgery) for women found to be carriers of gene mutations. These factors may affect physician decisions about discussing genetic testing with breast cancer patients. The National Cancer Institute has developed a directory, also available on the internet (CancerNet™ World Wide Web site), of genetic counselors (physicians, geneticists, and nurses) who accept referrals and a booklet ("Understanding Gene Testing") for health care providers who discuss genetic testing with patients.[19]

Future surveys should focus on oncologists and involve patients diagnosed more recently than 1995, because knowledge of and interest in genetic testing may be growing among unaffected relatives. Only surveys of all physicians involved with each breast cancer patient, and/or the patients (and their affected or unaffected relatives), can fully assess the frequency of discussions about genetic testing. Finally, evidence for differences in clinical and histopathologic characteristic of prognostic relevance (eg, younger age at onset, higher grade, and higher rate of second primary breast cancers) between patients who are carriers of BRCA1 *vs* BRCA2 carriers.[20–22] may lead to greater clinical interest in genetic testing of breast cancer patients.

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Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Review of the Connecticut State Tumor Registry

KHALIQUE S. ZAHIR, M.D., JACQUELYN A. QUIN, M.D., WILFRED BROWN, M.D., J. GRANT THOMSON, M.D., AND STANLEY J. DUDRICK, M.D.

ABSTRACT—*Background:* Although soft tissue malignancies of the upper extremity are rare, the management of these lesions has been controversial and the etiologic factors associated with the occurrence of these tumors are not well understood. The purpose of this study was to identify possible epidemiologic factors related to a recently noted rise in the occurrence of these tumors in the state of Connecticut.

***Methods:* The occurrence of upper extremity soft tissue tumors over the past 40 years was reviewed in the Connecticut State Tumor Registry. Demographic data collected included occupational history, residence, and presence of concomitant malignancies. Tumor histology, the extent of resection, and the incidence of recurrences were also noted. Factors associated with recurrence were identified using linear regression analysis.**

***Results:* During the 40-year study period, 359 patients having upper extremity soft tissue tumors were entered into the Connecticut State Tumor Registry. An increasing trend in the number of upper extremity soft tissue tumors was evident. Many patients were involved in heavy industry or related fields. Fibrosarcoma and liposarcoma were the most common tumor types, occurring in 111 (30.3%) and 48 patients (13.2%), respectively. Sixty-seven patients presented with a synchronous second primary malignancy of the breast (49 patients), lung (seven patients), or gastrointestinal tract (five patients). Most patients (69.9%) underwent local excision of the soft tissue tumors, with fewer undergoing wide excision (20.3%) or radical excision (9.7%). Recurrence, which occurred in 144 patients, was found to be associated with extent of resection, occupational history, and concomitant malignancy. Delineation of such risk factors may be helpful in identifying patients in whom aggressive management may decrease recurrence and improve survival.**

Introduction

THE diagnosis and optimal management of upper extremity soft tissue tumors may be challenging, as these relatively rare neoplasms account for less than 1% of adult malignancies.[1] Furthermore, little is known regarding associated risk factors for the development of these malignancies. Acquisition of such knowledge is impeded somewhat by virtue of their infrequent occurrence. In contrast, some of the risk factors for truncal soft tissue tumors have been identified; these include radiation exposure and certain occupational exposures.[2] The identification of associated risk factors for extremity tumors could potentially benefit the management of the patient with an upper extremity mass. Such masses, which may be mistakenly regarded initially as benign,[3] might be viewed with a higher index of suspicion by the clinician who recognizes an associated risk factor for malignancy. With earlier recognition and aggressive management, tumor recurrence might be reduced and survival improved.

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Table 1.—Occupational History

Occupation	Number (%)
Industrial	75 (20.9)
Engineering	63 (17.6)
Domestic	55 (15.4)
Professional	37 (10.3)
Clerical	26 (7.3)
Textiles	12 (3.4)
Unknown	60 (16.8)

Despite their relatively rare occurrence, several cases of upper extremity malignancies have been treated within several weeks in our institution, a 250-bed community hospital. St. Mary's Hospital is situated within geographic proximity to several industrial plants, and a large percentage of the local population has historically been involved in heavy industry. As a result, we were curious as to whether the recent increase in the number of cases of upper extremity soft tissue malignancies was simply coincidental, or if the incidence of these upper extremity tumors was actually increasing in this region. If the latter were the case, it would be helpful to identify any significant endemic or epidemiologic etiologic or associated factors. We hypothesized that the incidence of upper extremity soft tissue sarcomas in this region may have actually increased in recent years, possibly because of the strong influence of industrial exposure and/or environmental contamination. As a resource for this study, we examined data in the Connecticut State Tumor Registry, the oldest cancer registry in the nation. The statewide occurrence of upper extremity soft tissue tumors together with all available demographic data for this cadre of patients was reviewed for 40 years in four 10-year increments, starting with the calendar year 1950. Follow-up data continue to be evaluated and are current through 1996.

Materials and Methods

Records from the Connecticut Tumor registry were retrospectively reviewed from 1950 to 1990. The incidence of upper extremity soft tissue tumors was divided into four 10-year time frames: 1950-59, 1960-69, 1970-79, and 1980-89. Patient demographic data included patient age at presentation, gender, occupational history, town of residence, family history of malignancies, history of previous upper extremity trauma or of hazardous exposure, and, where applicable, tumor recurrence and cause of demise. Second primary malignancies were noted when present. Tumors were categorized by histological features and anatomical location. The surgical procedures performed were categorized as local, wide, or radical resection. Patients who presented with unresectable lesions or evidence of disseminated disease were not included in this review.

Table 2.—Histologic Tumor Types

Histology	Number (%)
Fibrosarcoma	109 (30.3)
Undifferentiated	65 (18.2)
Liposarcoma	47 (13.2)
Leiomyosarcoma	26 (7.3)
Rhabdomyosarcoma	23 (6.4)
Synovial	20 (5.6)
Kaposi's	15 (4.2)
Spindle cell	12 (3.4)
Lymphoma	11 (3.1)
Schwannoma	9 (2.5)
Malignant fibrous histiocytoma	9 (2.5)
Neurofibrosarcoma	8 (2.2)
Other	4 (1.0)

Linear regression was performed using a computer statistical software package CRUNCH (TexaSoft, Cedar Hill, Tex.) to determine if any demographic factors were associated with recurrence.

Results

Three hundred fifty-nine patients having upper extremity soft tissue malignancies were entered into the registry during the reviewed 40-year time span. One hundred ninety-seven patients were men (55%) and 162 patients were women (45%). The mean age was 52 years (range one to 96 years).

The largest number of patients per 10-year period presented during the most recent decade studied, 1980-89. An increasing trend in the percentage of the total 359 upper extremity soft tissue tumors was evident (Fig. 1)

Table 3.—Concomitant Tumors

Cancer Type	Number (%)
Breast	49 (13.6)
Lung	7 (1.95)
Gastrointestinal	5 (1.39)
Lymphoma	3 (0.84)
Colon	2 (0.56)
Prostate	1 (0.28)

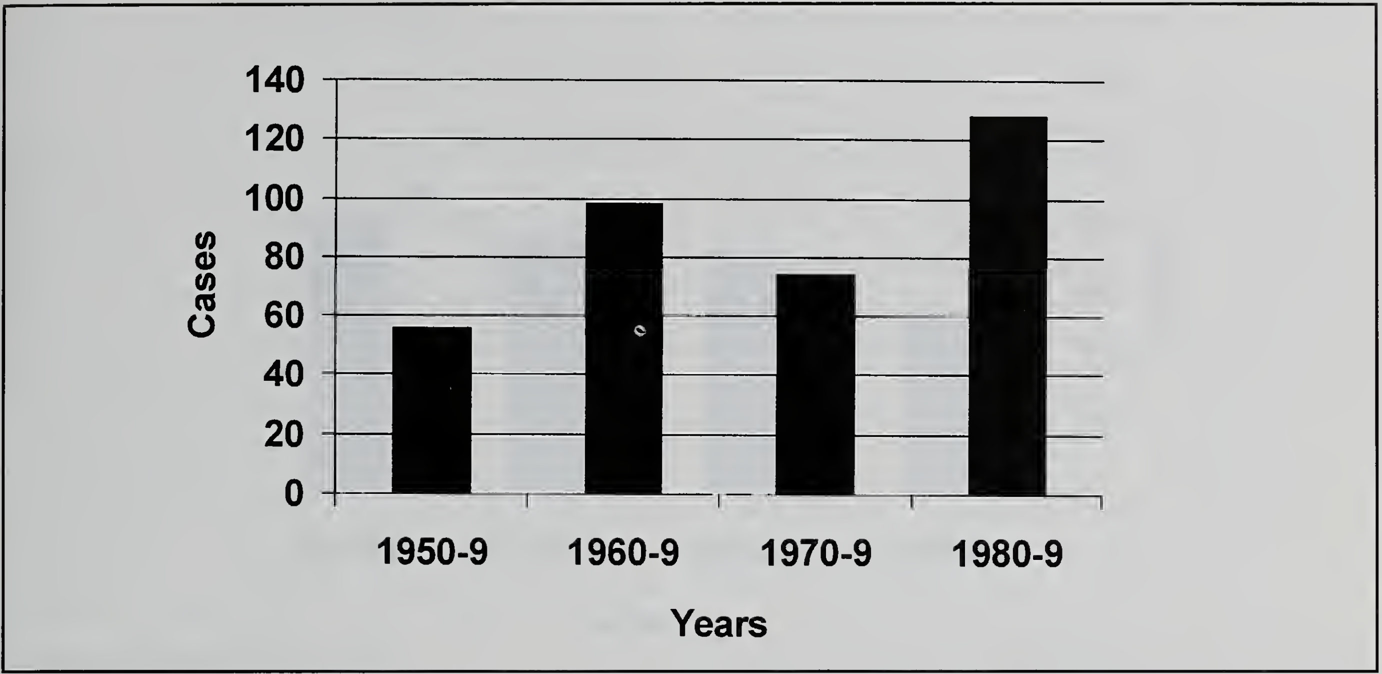

Figure 1.—Incidence of Upper Extremity Soft Tissue Sarcoma in Connecticut from 1950–1989

over the four decades reviewed, with the incidence of upper extremity soft tissue tumors for each of the four decades being 15.8% in 1950-59, 27.5% in 1960-69, 20.9% in 1970-79, and 35.8% in 1980-89.

The occupational histories of these patients are presented in Table 1. The largest cadre of patients was involved in industrial labor; however, this group comprised slightly less than 21% of the overall patient population. Included in this category were brass and copper mill workers as well as individuals involved in the processing of natural and synthetic rubber and other chemical substances. Engineers comprised 17.6% of the overall patient population; included in this group were individuals involved in chemical and manufacturing plants. Textile workers represented 3.4% of the patient population. The majority of occupations were not associated with industry, but represented a wide variety of activities including professional, clerical, and domestic work. Eight percent of the population were pediatric patients. Geographically, a significant concentration (over 70%) of the patients in the registry resided in the central portion of the state.

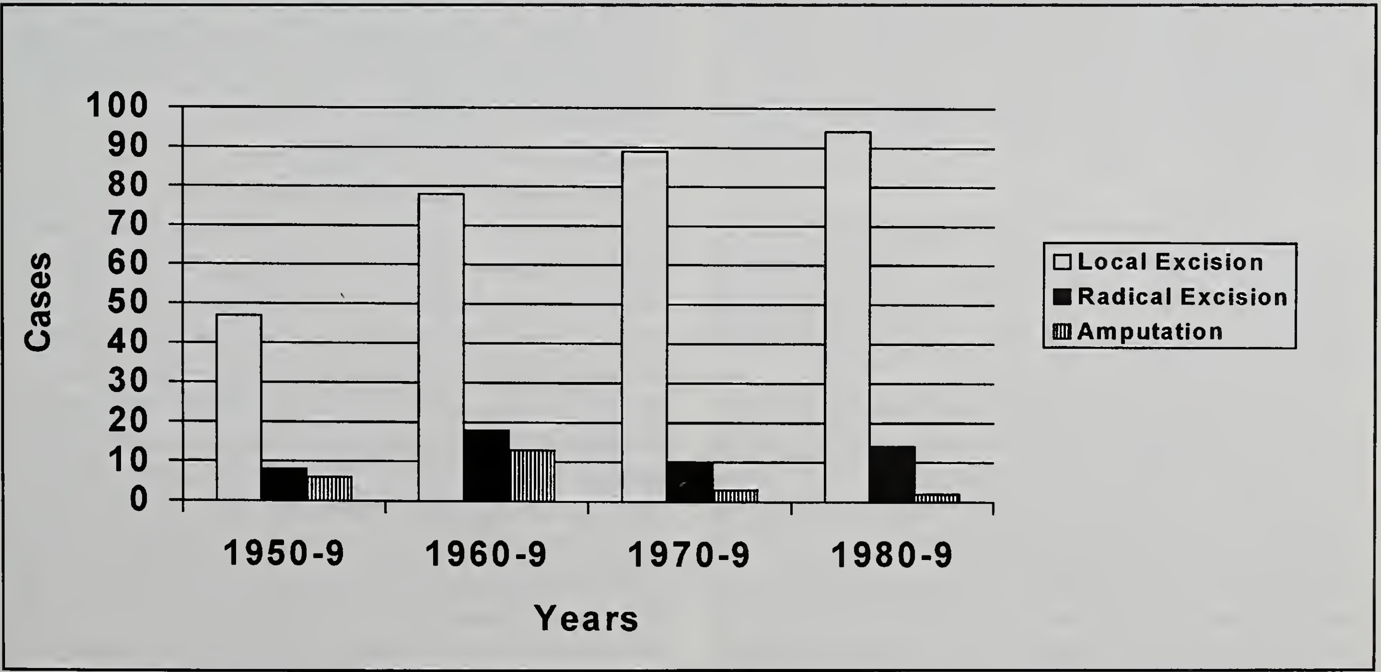

Figure 12—Initial Surgical Procedure for Upper Extremity Soft Tissue Sarcoma in Connecticut from 1950–1989

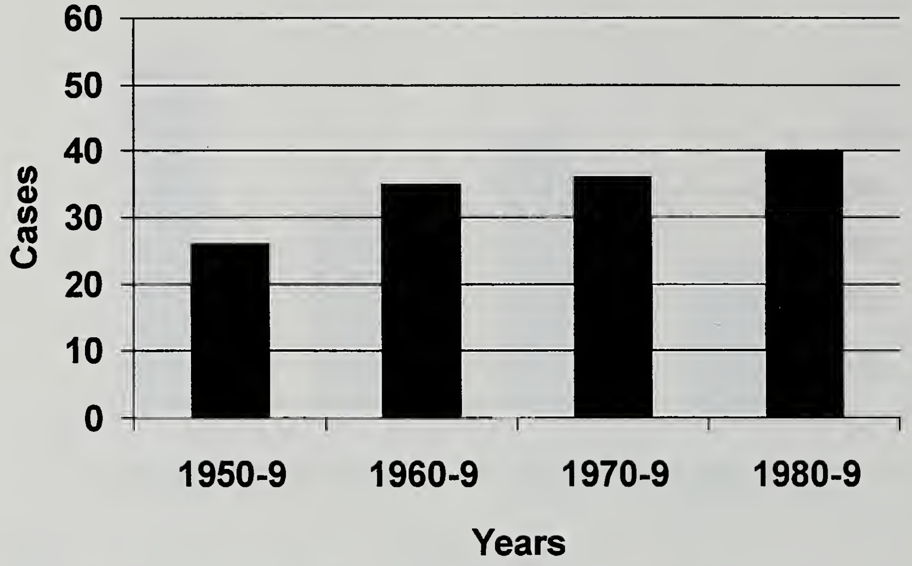

Figure 3.—Recurrence of Upper Extremity Soft Tissue Sarcoma in Connecticut from 1950–1989

The histologic types of tumor are presented in Table 2. Fibrosarcoma, the most common histologic type, occurred in 111 patients (30.3%). Sixty-five tumors were undifferentiated (18.2%). Forty-eight tumors were liposarcomas (13.2%). Less common tumors included neurofibrosarcoma, synovial, spindle, malignant fibrous histiocytoma, and Kaposi sarcomas; collectively, these tumor types were manifested in approximately 19% of the patient population studied.

The number of tumors which involved the right (183 patients) and left (176 patients) upper extremities was nearly equal. Most tumors were located proximally, in the shoulder (115 patients, 32%) and upper arm (100 patients, 28%). Relatively fewer tumors were located distally, in the forearm and hand (66 and 44 patients, 18.5% and 12.3%, respectively). The fewest cases were located in the digits (33 patients, 9.2%).

Sixty-seven patients presented with a synchronous second primary malignancy (Table 3). The most commonly occurring second primary neoplasm was breast cancer (49 patients), followed by pulmonary and gastrointestinal tumors (seven and five patients, respectively).

The majority of patients (69.9%) underwent local excision of the soft tissue tumors during the overall 40-year period studied. Wide excision was performed in 73 patients (20.3%); whereas, radical excision or amputation was the operation of choice in 35 (9.7%) patients (Fig. 2). A steady rise in the number of patients who underwent local excision was evident over the four decades, and relatively few patients underwent radical excision or amputation during the time period studied.

Recurrence

Of the 359 patients in the study, 144 experienced a recurrence. Recurrent tumors were tabulated for each decade based on the type of surgical resection performed (Fig. 3). Of the tumors resected in 1950-59, 48% recurred. Slightly lower percentages of recurrence were seen during the 1960-69 and 1980-89 periods (37% and 31%, respectively). An unexpectedly high number of recurrent cases (46%) was seen from 1970-79 (Fig. 3).

Multivariate linear regression revealed three independent factors which correlated with tumor recurrence: 1) the extent of the surgical procedure, 2) the occupational history, and 3) the presence of a synchronous second primary tumor. Tumor location did not correlate significantly with recurrence.

Discussion

In comparison with other malignancies, sarcomas and other soft tissue malignancies are not as well described in terms of epidemiologic risk factors and etiology. The literature on soft tissue tumors of the extremities is even more sparse in this regard, as we did not find any reports which specifically addressed associated risk factors. It is generally known, however, that occupational exposures appear to increase the risk of developing soft tissue malignancies. The study by Wingren et al, which identified occupations associated with soft tissue tumors, reported an increased risk for malignancy in gardeners, railroad workers, and construction workers.[4] Our study also found that certain occupations are well represented within this patient population, notably industrial workers and engineers. Presumably a high percentage of patients with such work histories may have had chemical or metallic exposure as an occupational hazard. The geographic distribution of these patients also supports an association of these tumors with industry because an inordinate concentration of tumors occurred in patients living in the central portion of Connecticut along the Naugatuck River Valley where a large number of industrial and manufacturing plants are in operation. Because a specific history of hazardous exposure could not be ascertained in all cases, the association is only observational, and definitive statements cannot be made regarding actual relative risk with respect to these factors in this retrospective study.

The time frame studies did support our suspicion that the number of cases of upper extremity malignancies has slowly increased during the recent 40-year period studied in the State of Connecticut at a rate that has exceeded population growth during the same time period. Meanwhile, the census has been rather consistent in Connecticut during the same four decades.

An interesting, unexpected finding in our study was the unexplained high rate of recurrence, especially in patients with industrial exposure. Unfortunately, tissue grade was not recorded in this study; however, one may speculate that industrial exposures may have predisposed patients to a higher grade, more aggressive malignancy.

Although not the focus of this study, a correlation was found between the extent of surgical resection and the incidence of recurrence. The increased recurrence rate following limited resections is not altogether surprising. Studies have shown that limited limb resections performed for the purpose of preservation of function are associated with higher recurrence rates. In their study of 108 patients with localized, resectable upper extremity soft tissue tumors, Collin et al showed an increased local recurrence in patients who presented with inadequate surgical margins.[5] Increased recurrence rates were significantly higher in patients who underwent limb-sparing procedures. Their study also showed that less than half of the patients treated with limb-sparing surgery had adequate margins.

Other authors have supported radical primary excision in an effort to reduce local recurrence of these tumors. Creighton et al retrospectively studied 126 patients with primary sarcomas of bone (45 patients) and soft tissue (61 patients).[6] They found that radical primary excision decreased local recurrence with a subsequent decrease in metastasis. Steinberg et al, studied 18 patients with epithelioid sarcoma, 12 of whom were treated with marginal resection and adjuvant radiation, chemotherapy, or both. At a mean follow-up of six years, six of these patients had recurrence of disease, five of whom had died of the disease by the time of follow-up. Of the six patients who were treated with wide or radical excision, one patient suffered local recurrence and one patient presented with metastasis at a mean follow-up of seven years.[7]

Although radical excision appears associated with decreased recurrence, other authors argue that less extensive procedures may be equally efficacious while preserving limb function, especially when combined with adjuvant therapy, such as radiation or chemotherapy. Talbert et al retrospectively studied 78 patients with extremity soft tissue sarcomas who were treated with conservative surgery and radiation. Recurrence was seen in 19% of patients, but 80% (12/15) of these patients were successfully salvaged. Limb sparing-surgery was ultimately successful in 68% of patients, and patients with upper extremity lesions treated by limb-sparing surgery fared better than those treated by amputation in terms of functional outcome. These authors concluded that conservation surgery is acceptable and may even be preferable to amputation.[8]

Serpell et al identified factors which might predispose to tumor recurrence and decreased survival in patients with upper extremity malignancies. In his study of 51 patients with soft tissue sarcomas of the upper limb, deep fixation, origin of tumor in the forearm, and previous local recurrence were associated with decreased survival. Of note, 75% of patients had presented with local recurrence after treatment elsewhere implying an incomplete initial resection.[9]

Fleegler et al also emphasized the importance of complete, precise treatment of these tumors on initial presentation. Such treatment requires a high index of suspicion for malignancy in the seemingly benign upper extremity mass.[10]

Our study demonstrates that the extent of surgical excision affected the rate of recurrence; local resection may result in inadequate surgical margins with higher risks of recurrence. Nonetheless, an increasing trend in the use of local excision in resection of tumors of the upper extremity was evident during the four decades studied, whereas the number of radical excisions and amputations declined.

Also noted in our study was a high number of recurrences in patients who presented with a synchronous second malignancy. The mechanism by which an associated malignancy increases the risk for upper extremity soft tissue recurrence is unclear. No individuals in our patient population were identified with the Li Fraumeni syndrome although breast cancer was the most common concomitant tumor discovered along with an upper extremity soft tissue sarcoma. Gallo et al recently suggested that subjects with increased susceptibility to carcinogens after exposure to tobacco or alcohol are at higher risk for multiple cancers in which one of the most common genetic events is aberrant p53 expression.[11] It is anticipated that advances in the knowledge of tumor biology will elucidate this elusive mechanism in the future.

We have shown that the number of cases of upper extremity soft tissue tumors in Connecticut has risen steadily and beyond that expected for the population growth during a recent 40-year period, and that a large number of these cases appear to be associated with heavy industry within the state. In addition, based on an analysis of this population of patients, a history of an industrial occupation, a concurrent secondary malignancy, and/or conservative surgical excision appears to correlate directly with an increased risk of recurrence. These associated factors should alert the clinician to a higher index of suspicion for malignancy in the patient who may present with an otherwise benign appearing upper extremity mass.

Although a broad time period has been reviewed and the standard of care has obviously changed over time, it appears that early aggressive management may decrease the chance of local recurrence and ultimately improve long-term survival in patients with upper extremity soft tissue malignancies.

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A Case Report:
Extralobar Pulmonary Sequestration in a Newborn

HELEN M. KELLETT, M.D., DAVID P. NEUMANN, M.D.,
AND ROBERT J. SCHOLL, M.D.

EXTRALOBAR pulmonary sequestration is a rare congenital anomaly. Most cases present in the first six months of life, usually in the newborn period, with symptoms of respiratory distress.[1–5] We report a case of extralobar pulmonary sequestration in a newborn.

A full-term male infant was born to a gravida 2 para 2 female after an uncomplicated pregnancy. His Apgar scores were seven and nine at one and six minutes, respectively. He did well and was breast feeding when at 20 hours of age he became tachypneic. A chest film (Fig. 1) revealed a mass posteriorly located at the base of the left hemithorax causing a slight shift of the mediastinal structures. An ultrasonogram (Fig. 2) of the left lower thorax showed a well-marginated, homogeneous, echogenic intrathoracic mass. A thin echogenic rim was documented around the periphery of the lesion. A computed tomographic scan of the chest (Figs. 3A and 3B) confirmed a 6.5 cm mass in the left hemithorax lying above the diaphragm. Small vessels were identified converging towards the thoracic aorta. A thoracic and abdominal aortic angiogram (Fig. 4) documented a large supplying vessel arising from the thoracic aorta. The venous drainage appeared to be the hemiazygous system.

Discussion

Pulmonary sequestration is defined as an aberrant mass of pulmonary tissue that does not communicate in a normal fashion with the tracheobronchial tree and receives its blood supply via an anomalous systemic artery.[1] The arterial supply is usually from the descending thoracic aorta or from the abdominal aorta or one of its branches.[1] Pulmonary sequestrations are categorized as either intralobar or extralobar. They are thought to be congenital in origin, yet many believe the intralobar type is acquired.[2–4] Some authors consider sequestrations to be part of a spectrum of bronchopulmonary foregut malformations, but others disagree.[4]

Intralobar sequestration is the most common form, accounting for 75% to 85% of all sequestrations.[2] The sequestered tissue is within the normal lung and its pleural cover but lacks a normal bronchial connection. Most patients are symptomatic by 20 years of age,[1,3] presenting with cough, sputum production, and recurrent pneumonia.[3] Infection and/or communication with normal lung is not uncommon.[1] It occurs equally in male and female patients, and associated congenital anomalies are uncommon.[1] Most cases occur in the lower lobes, usually on the left side.[1–4] The arterial supply is usually from the descending thoracic aorta and may be multiple.[3] In 95% of cases, the venous drainage is via pulmonary venous system.[3]

Extralobar pulmonary sequestration is a congenital lesion and accounts for 15% to 25% of all sequestrations.[2] The sequestered tissue has its own pleural covering.[1] The majority of cases (61%) are diagnosed in the first six months of life.[2,3] Infants present with respiratory distress, cyanosis, and feeding difficulties.[2,3] Congestive heart failure and pulmonary overcirculation are recognized complications, especially in infants.[3] Unlike the intralobar variety it rarely presents with recurrent pulmonary infection and/or communication with the normal lung.[1] Extralobar sequestration may manifest *in utero*, associated with polyhydramnios or fetal hydrops.[2] It occurs more frequently in males with a male-to-female ratio of

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4:1.[1,2] Approximately 65% of cases have associated congenital anomalies with congenital diaphragmatic hernia being the most common associated anomaly.[2,3]

Extralobar pulmonary sequestration most commonly is found between the lower lobe and the diaphragm. There is an even greater left-side preponderance than seen with the intralobar type. These lesions may also be seen within the diaphragm, mediastinum, pericardium lung, or even below the diaphragm.[2,3] The blood supply is typically from systemic arteries with vessels from the thoracic or abdominal aorta responsible for 80% of cases.[2] Multiple feeding arteries are identified in 20% of cases.[2] The venous drainage (>80%) is systemic via the azygous, hemiazygous, or interior vena cava.[3]

The radiologic diagnosis of extralobar pulmonary sequestration is made by identifying a systemic vascular supply. In the past, angiography has been the most widely utilized modality; however, other imaging studies including computed tomography (CT), ultrasound, and magnetic resonance imaging (MRI) may document the vascular anatomy. The typical chest radiographic appearance of an extralobar pulmonary sequestration is that of a single well-delineated, homogenous, triangular opacity in the lower thorax contiguous with the posterior medial

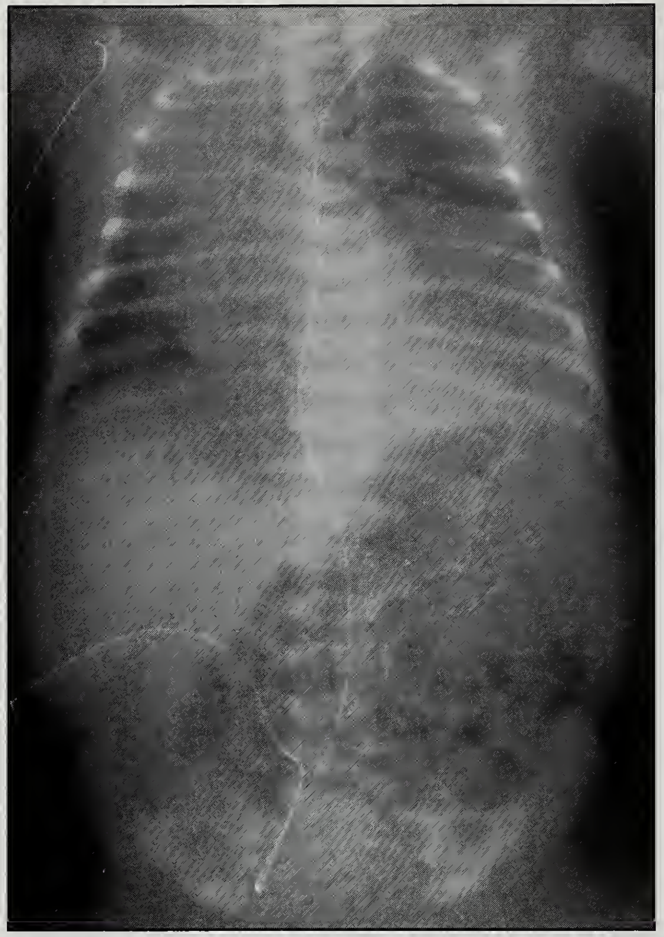

Figure 1.—Extralobar sequestration in a new-born boy. Chest radiograph shows a soft tissue mass in the inferior left hemithorax and slight mediastinal shift to the right.

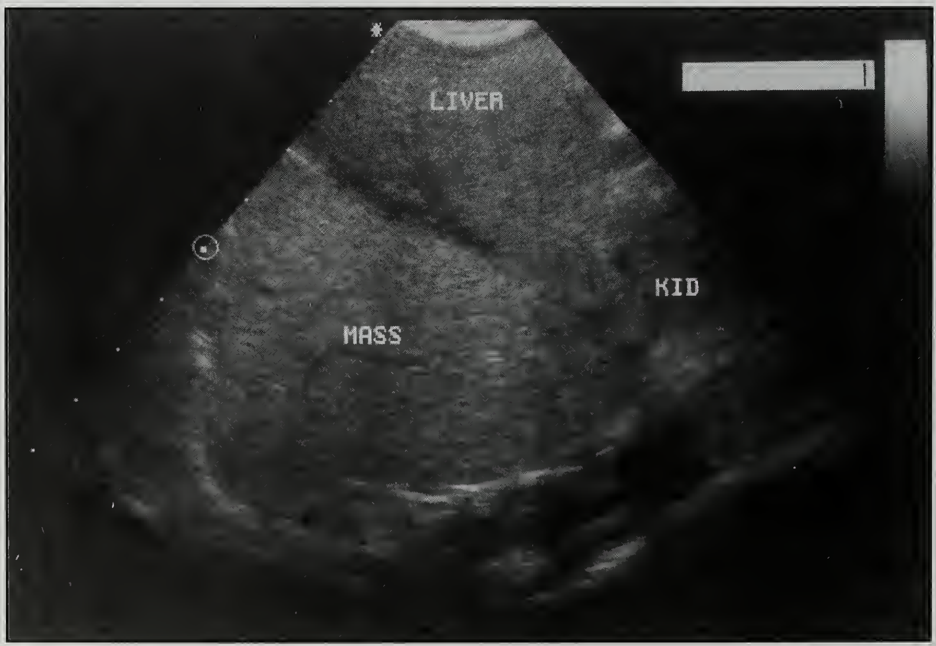

Figure 2.—Longitudinal chest sonogram shows a well-marginated, homogeneous echogenic mass above the diaphragm.

hemidiaphragm.[2] Other findings include a mass elsewhere in the thoracic cavity, associated pleural effusion, or associated changes of high-output congestive heart failure.[2] An upper gastrointestinal series may be useful if a communication with the esophagus or stomach is suspected.[2] The diagnosis of extralobar pulmonary sequestration rests on documenting the aberrant systemic arterial supply and venous drainage, and often requires angiography. Ultrasonography of an extralobar sequestration typically reveals a well-marginated, echogenic homogenous intrathoracic mass. A thin, echogenic rim around the sequestered lung has been described.[2] Chest CT typically reveals a homogenous and well-marginated soft tissue mass. Cystic areas as well as calcifications within the mass have been described.[4] Emphysematous changes in adjacent the lung have also been documented.[4] MRI may allow noninvasive visualization of the feeding arteries and draining veins, precluding the need for angiography.[2]

The therapy for extralobar pulmonary sequestration is surgical excision. The prognosis for patients with isolated extralobar sequestration is usually favorable, but as is expected, is variable in those cases with associated anomalies.

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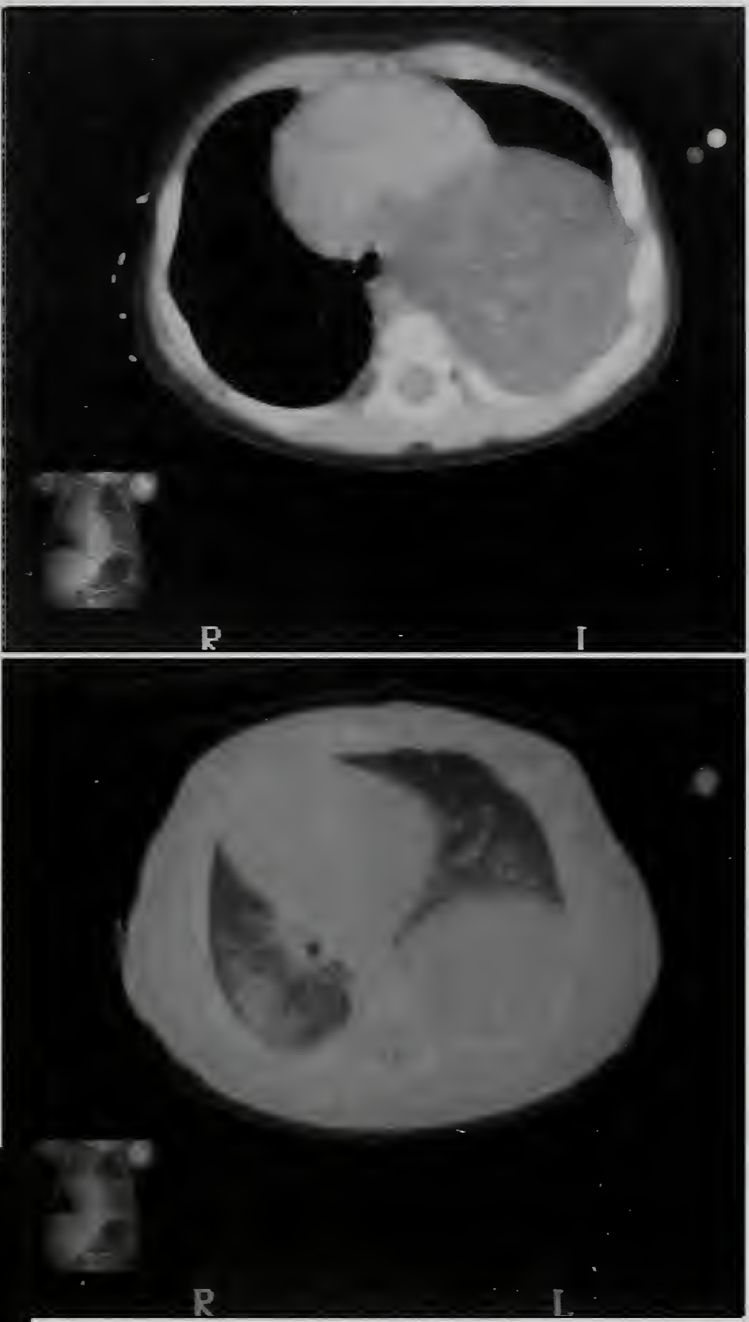


Figure 3a and 3b.—Mediastinal (3a) and lung (3b) windows of a chest CT confirm a soft tissue mass as the base of the left hemithorax.

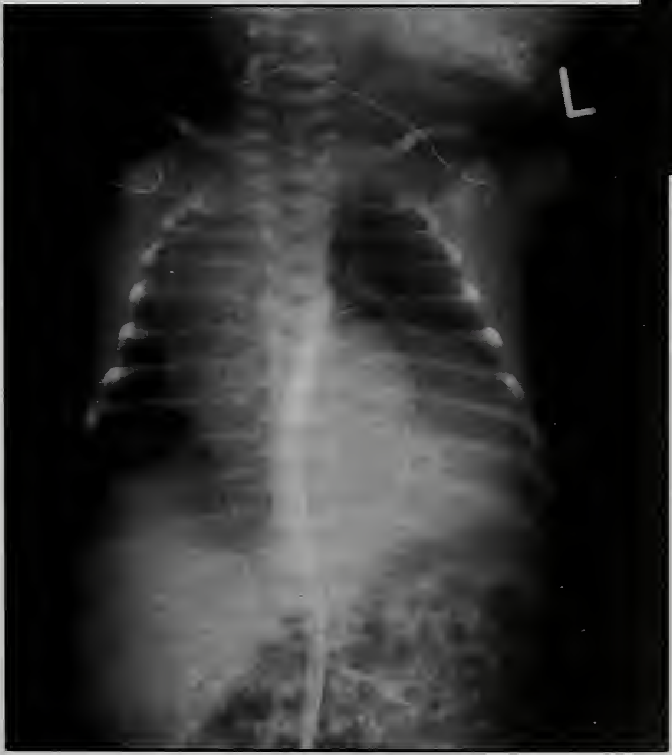
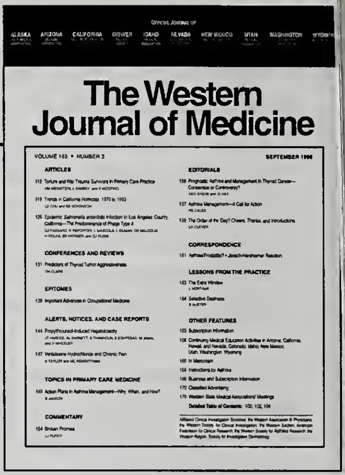


Figure 4.—A thoracic and abdominal aortic angiogram shows that the vascular supply is from the thoracic aorta.



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Important Advances in Clinical Medicine Family and General Practice

Jan 0. Sonander, M.D. and Daljeet S. Rai, M.D., Section Editors

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in family and general practice. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in family and general practice that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Family and General Practice of the California Medical Association, and the summaries were prepared under the direction of Drs. Sonander and Rai and the Panel.

Advances in Dementia Management

DEMENTIA is a syndrome of progressive cognitive and functional decline that affects 5% to 10% of the U.S. population aged 65 and older. Its incidence doubles every five years after age 65.

Clinicians often underestimate the amount of impairment that older patients experience in daily living. Only about one half of patients with dementia are identified by primary care physicians using the routine history and physical examinations. Early recognition of dementia may allow for treatment of reversible causes, amelioration of partially reversible causes, and delay of functional disability for some irreversible causes of dementia. Approximately 10% to 15% of cognitive impairment in older adults is due to treatable conditions such as hypothyroidism and drug toxicity. Early identification of patients with dementia allows the patient and family to plan for future long-term-care services, and to take the opportunity to participate in trials of new, potentially helpful therapies. Unrecognized dementia may result in inappropriate use of emergency services and unneeded patient/family discomfort.

The Agency for Health Care Policy Research (AHCPR) recently issued clinical practice guidelines to assist health care professionals in the early and accurate identification of Alzheimer's disease, the most common cause of dementia. Because dementia is often misdiagnosed or unrecognized in its early stages, the guidelines identify early symptoms and signs of dementia, guiding early assessment. Certain symptoms, such as problems with spatial ability and orientation or difficulties in learning, language, and handling complex tasks, distinguish early-stage dementia from normal aging and from other syndromes that affect cognition such as depression or delirium. These triggers prompt early assessment such as focused history, physical, functional, and mental status assessment. Using these decision support guidelines, primary care clinicians may identify the cause of dementia with greater accuracy.

Specific identification of Alzheimer's disease allows early treatment with newer agents that may better control behavioral signs and symptoms, improve cognitive function, and slow disease progression. Patients suffering from dementia commonly suffer from behavioral symptoms such as depression, anxiety, psychosis, aggression, agitation, and apathy. More effective medications are now available for the treatment of these conditions resulting from expanded Medicaid formulary inclusion of existing effective agents (such as serotonin reuptake inhibitors,

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SSRIs), the recognition that antiepileptic drugs have utility in behavior management (carbamazepine, valproic acid), and the introduction of newer psychotropics with fewer side effects (respiradol, olanzepine).

Therapies thought to enhance cognitive function in Alzheimer's disease by restoring functional deficits in neurotransmission, increasing cholinergic transmission, are available. Two cholinesterase inhibitors (tetrahydroaminoacridine and donepezil) show promise, both of which have been approved by the Food and Drug Administration. The use of each has demonstrated significant improvements in cognition and function, delaying suffering and costly use of long-term-care resources. There is modest evidence to support the benefit of selegiline, a monoamine oxidase inhibitor, and Vitamin E, which have been shown to cause mild improvement in cognitive function and behavior.

It is crucial that clinicians carefully evaluate patients with suspected dementia, obtaining information from informants, perform appropriate laboratory and imaging tests, and render a specific dementia diagnosis. Patients should then be monitored for intercurrent medical problems, which frequently present as a worsening of dementia symptoms. Such problems should be treated, and dementia symptoms monitored. Improving sensory input can result in diminishing dementia symptoms and improved function. Environmental modification such as improving lighting, decreasing noise levels, and controlling wandering while promoting environmental exploration may lead to improved function. Clinicians can ease exhaustion and conflicts by teaching patients, families, and caregivers about available community resources that can help with coping with the illness and planning long-term care services. These include Area Agency on Aging (inhome and community services; nutrition), Alzheimer's Disease Centers (clinical services; research and education), and the Alzheimer's Association (education; support groups; adult day care; respite).

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Treatment for Human Immunodeficiency Virus (HIV) Infection

As recently as 1993 and the International AIDS Conference in Berlin, the future of HIV antiretroviral therapy had darkened to a depressing gray. The Concorde Study questioned the long-term value of zidovudine (AZT) monotherapy for asymptomatic individuals, while other studies involving people with advanced disease found minimal benefit from switching to, or adding another, antiretroviral therapy. In the last four years, however, antiretroviral therapy has experienced a revival. Plasma HIV RNA testing allows close monitoring of HIV therapy, which has become more effective with the development of a more potent class of antiretrovirals, protease inhibitors. After years of being in desperately short supply, hope can again be found within offices of physicians treating HIV disease

Multiple studies have demonstrated the predictive value of plasma HIV RNA levels, commonly referred to as "viral loads." This testing measures the amount of ongoing HIV replication, which correlates with the rate of CD4 cell destruction. In contrast to CD4 testing—a static measure of immune system damage—this test is a dynamic marker predicting the risk of future damage and, therefore, disease progression. Perhaps the most valuable role of HIV RNA testing, when used along with CD4 testing, is to help individualize the starting and changing of a patient's antiretroviral regimen.

Recent developments in antiretroviral drugs have also been dramatic. As of the Berlin Conference, only four drugs (zidovudine, didanosine, zalcitabine, and stavudine) were readily available, and all four were in the same class (nucleoside reverse transcriptase inhibitors). At present, 11 antiretrovirals have been approved by the Food and Drug Administration, including a new nucleoside (lamivudine) and six drugs in two new categories. Saquinavir, ritonavir, indinavir, and nelfinavir are protease inhibitors, which act on protease, another enzyme essential to the HIV life cycle. Nevirapine and delavirdine are non-nucleoside reverse transcriptase inhibitors (NNRTIs), which inhibit reverse transcriptase, but have a different chemical structure than nucleosides. Protease inhibitors are potent, having a monotherapy capacity to reduce viral load by 1- to 2-log; other drugs typically yield only a 0.5- to 1-log reduction.

Generally, a protease inhibitor is used in combination with at least two other drugs—a mode of treatment dubbed "highly active antiretroviral therapy" (HAART). The goal of HAART is to reduce plasma HIV RNA assays to below a detectable level (around 100–500 copies/mL, depending on technology used). The short-term benefit of HAART has been well demonstrated, perhaps most dramatically in a ritonavir study that found a survival advantage for people with advanced disease randomized to receive ritonavir along with whatever drugs they were receiving. Pending further research, long-term clinical benefit remains largely theoretical. Two advantages of prolonged suppression of HIV are anticipated. A dramatic reduction in the rate of CD4 cell destruction should lead to a marked slowing in HIV progression, and the synergistic activity of a multiple-drug regimen should significantly delay the development of drug resistance.

Now more than ever, drug resistance is a major concern. At one extreme of antiretroviral potency—the absence of any drug therapy—HIV will not experience the selective pressure that leads to resistance. At the other extreme—a highly potent therapy that suppresses HIV to undetectable levels—mutation to a resistant strain is dramatically slowed. The risk of resistance is greatest when potency is intermediate, when a regimen uses weaker drugs or is prescribed in insufficient doses, or because a person intermittently misses doses, leading to prolonged troughs in drug serum levels.

To address this last concern, the primary care physician can foster patient compliance in several ways: 1) evaluating each person's ability to adhere to a given regimen; 2) pretreating substance abuse and social instability; 3) educating about a new regimen (including a detailed schedule of dosing including food and water restrictions, and information about drug interactions and toxicities); and 4) suggesting strategies that will support adherence (a pillbox, a note on the bathroom mirror or refrigerator, an alarm-watch, extra supplies of medications at places frequently visited, enlisting support from friends).

The selection of a given regimen should combine a knowledge of a person's antiretroviral history (including the effect of drugs on CD4 and viral load counts, toxicities, and the likelihood of resistance) with plans about what to do if the regimen fails. This increasingly complex task has been reviewed recently by two panels: one convened by the National Institutes of Health, focusing on principles of therapy; the other by the Department of Health and Human Services and the Henry J. Kaiser Family Foundation, offering more concrete guidelines for antiretroviral prescription. The complexity of these documents supports a growing consensus that antiretroviral management should be done by physicians with considerable HIV experience or by primary care doctors who consult frequently with a specialist.

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Advances in Diabetes Management

DIABETES is a common yet complex set of medical conditions unified by high plasma glucose. It can result from insulin deficiency, insulin resistance, or both. Advances in both the diagnosis and treatment of diabetes have revolutionized the disease over the past few years. These advances come from a new conceptualization of the disease, clinical trial data, and the development of new treatments. These advances have put diabetes at the forefront of quality assurance efforts.

The recent report from the American Diabetes Association's Expert Committee on the Diagnosis and Classification of Diabetes Mellitus presents several advances. Perhaps the most important is an adjustment of the diagnosis of diabetes, specifically the lowering of the fasting plasma glucose level needed to make the diagnosis. In order to have diagnostic criteria be more internally consistent, the new criteria state that diabetes should be diagnosed if a person has a fasting plasma glucose 2,126 mg/dL (7.0 mmoL/1) or a 2-hour plasma glucose 2,200 mg/dL during an oral glucose tolerance test or a glucose measurement 2,200 mg/dL in a person with symptoms. The committee's recommendation against universal screening for gestational diabetes (and in favor of more selective screening) has met with general enthusiasm, while the recommendation to consider screening all adults over 45 years old had mixed reviews.

Treatment advances have come from two sources, one philosophical, the other based on specific drug use. First, the landmark Diabetes Control and Complications Trial (DCCT) trial confirmed that aggressive management of blood glucose leads to a reduction in diabetic microvascular complications (nephropathy, neuropathy, and retinopathy.) The trial's findings are limited by the young age of the participants (too young to measure cardiovascular outcomes, thus leaving the potential benefits of glycemic control on cardiovascular endpoints an unresolved question) and the difficulty of translating the results—performed on patients with type 1 diabetes—to those with the more common type 2 diabetes. Still, most clinicians take the DCCT results as an indication to push for tighter control of blood glucose in diabetic patients.

Therapeutic advances include new uses for old medications (such as bedtime NPH insulin) as well as new formulations. Oral hypoglycemic agents are achieving increased success with the introduction of second generation sulfonylureas, biguanides, α-glucosidase inhibitors, and troglitazone. The α-glucosidase inhibitors exert their activity in the gastrointestinal tract by reversibly inhibiting the enzymatic cleavage of complex carbohydrates to simple absorbable sugars. An α-glucosidase inhibitor may be given as monotherapy with diet or in combination with diet and a sulfonylurea drug. Troglitazone is another new oral agent unrelated to sulfonylureas, biguanides, and or glucosidase inhibitors. Troglitazone increases the body's sensitivity to insulin. When used in patients with type 2 diabetes, troglitazone not only decreases fasting blood glucose but also favorably affects the patients' lipid profile and lowers plasma insulin levels, both changes likely to improve cardiovascular risk.

Monitoring the care provided to patients with diabetes can provide insights into quality of care issues. National groups such as the National Committee for Quality Assurance (NCQA), with its Health Plan Employer Data and Information Set (HEDIS) assessment, and the Foundation for Accountability (FACCT) have focused on diabetes. For example, the current HEDIS 3.0 evaluates how frequently patients with diabetes receive eye exams, with other measures being tested for possible inclusion in the future. FACCT's list of quality measures in diabetes is even more extensive.

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Bisphosphonates in the Treatment of Osteoporosis

OSTEOPOROSIS, a bone disease characterized by low bone density and micro-architectural deterioration, causes 1.3 million fractures annually. Each year, osteoporotic hip fractures alone are responsible for almost 30,000 deaths, an estimated 1,300,000 home health care visits, and nearly 33,000,000 nursing home days. Collectively, osteoporotic fractures cost the nation more than $13 billion.

Epidemiologically, osteoporosis affects those over 65 years of age, the fastest-growing segment of our population. In 1980, 11% of Americans were over 65. The percentage is now nearing 14 and is expected to double by 2050. Clearly, the need for safe, effective therapy is high.

Bone resorption followed by bone formation are the sequential metabolic events that make up the bone-remodeling cycle. In the first three decades of life, total body bone mass increases because more bone is formed during each remodeling cycle than is resorbed. By the middle of the fourth decade of life, resorption outpaces formation and bone mass gradually declines.

Current pharmacologic therapy to treat osteoporosis reduces bone resorption. The three classes of drugs categorized as antiresorptive agents are estrogens, calcitonin, and bisphosphonates.

The bisphosphonates, formerly called diphosphonates, are compounds composed of two phosphate groups attached to a central carbon atom. The mechanism by which bisphosphonates inhibit bone resorption is incompletely understood. Some evidence suggests a direct disruption of the osteoclasts' intracellular structures leading to diminished metabolic activity and perhaps cell death. Other studies support an interruption in the differentiation of the osteoclast precursor to mature osteoclast.

Regardless, decreased bone resorption is detectable within days of an oral administration. This allows bone formation to occur without bone resorption, resulting in a net acquisition of bone. However, this uncoupling of formation from resorption is not indefinite and a new equilibrium is achieved, albeit at an overall lower level of bone turnover. While current evidence suggests that bisphosphonate-treated bone can appropriately remodel, repair damage, and heal fractures, more data will be needed before their long-term safety is demonstrated.

Gastrointestinal absorption of bisphosphonates is poor, mandating taking the medication on an empty stomach and with tap water only. What little drug is absorbed is cleared from the plasma within six hours. Nearly 50% of the absorbed amount is bound to bone. Within this compartment, bisphosphonates remain for prolonged periods; the half-life of alendronate is calculated to exceed 10 years.

The beneficial effect of orally administered bisphophonates on bone mineral density has been firmly established. Placebo-controlled double-blind studies of intermittent cyclical etidronate treatment of postmenopausal women demonstrated an approximate 5% gain in lumbar bone mineral density. Most of the gain was achieved in the first year, but extension studies have confirmed additional slight increments in bone mineral density. Etridonate was given orally for only the first two weeks of each three-month period, since prolonged daily administration of etidronate causes osteomalacia.

Pamidronate, about 10-fold as potent as etridonate at inhibiting bone resorption but available in this country only for intravenous administration, has been shown to increase bone mineral density of the lumbar spine and femoral trochanter by 7 and 5.4%, respectively, following two years of daily, oral administration.

Two large studies comparing daily alendronate (about 500- to 1,000-fold more potent than etidronate) with placebo have recently been published. In one study, 2,027 postmenopausal, osteoporotic women with at least one vertebral fracture were randomly assigned to receive alendronate, 5 mg daily for two years followed by 10 mg daily for one year, or placebo. After three years, the alendronate group showed a significant increase of femoral neck, total hip, and lumbar spine bone mineral density of 4.1, 4.7, and 6.2%, respectively, over the placebo control. Another study randomized 478 postmenopausal women with osteoporosis to placebo or three alendronate regimens. After three years, the 10 mg per day alendronate group increased bone mineral density at the lumbar spine, femoral neck, and femoral trochanter 9.6, 4.7, and 7.4%, respectively, over the placebo group.

Although demonstrating increased bone mineral density is valuable, the real litmus test of clinical efficacy is fracture reduction. The data are not overwhelming, but estrogen therapy is generally believed capable of significantly decreasing the incidence of hip fracture. Only one study is large enough and designed to specifically evaluate the effect of a bisphosphonate on fracture evidence. Mentioned above, this study of 2,027 postmenopausal osteoporotic women demonstrated reduction of fracture incidence at vertebra, hip, and wrist of 46, 51, and 44%, respectively, in the alendronate-treated group compared with the placebo-treated group.

But gains may come at a price. Aside from inducing osteomalacia, etidronate may cause gastrointestinal problems in a small percentage of patients. The aminobisphosphonates are capable of causing more severe gastrointestinal side effects but do not cause osteomalacia. Of greatest concern is their capacity to induce esophageal lesions. A recent report identified three patients with severe esophagitis from alendronate (an aminobisphosphonate).

The bisphosphonates are an important class of drugs for treating postmenopausal osteoporosis. Although drugs within this class differ from one another, they have proven capacity to increase bone mineral density, and one agent (alendronate) reduces fracture incidence. In this country, two compounds are available for oral administration: etidronate is taken intermittently, 400 mg per day for two weeks followed by 11 weeks of treatment with calcium and vitamin D. Alendronate is dosed daily at 10 mg and taken on an empty stomach with tap water. To reduce the risk of esophageal damage, it should be taken with at least 6 to 8 ounces of water and the patient must remain upright for at least 30 minutes and until the first meal of the day has been eaten.

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Obesity as a Chronic Disease

OBESITY is usually considered a lifestyle disease. Those who are morbidly overweight are often regarded as weak in character or lacking discipline. Judgmental attitudes against the obese are pervasive in society and are just as harmful as other forms of social prejudice.

Obesity should be recognized as an important chronic disease, much like hypertension, hyperlipidemia, and type 2 diabetes. Like those diseases, obesity is a complex interplay of genetic, metabolic, and psychosocial factors.

The importance of obesity has been recently clarified. While more than 400,000 premature deaths per year in the U.S. are attributed to smoking, overeating and lack of physical activity come in at a close second, accounting for 300,000 premature deaths per year. In the past, obesity without other co-morbidities has been considered a relatively benign condition. The physiology of being overweight, however, directly contributes to elevated blood pressure, hyperglycemia, and a high-risk lipid profile.

Like other complex chronic diseases, the management of obesity requires a multidisciplinary program, combining lifestyle modifications with the possibility of pharmacotherapy. A team approach, extensive patient education, and regular long-term follow-up are hallmarks of therapy.

The goal in treating obesity is to achieve a healthier weight, not the elusive ideal weight. A 10% reduction in weight may result in dramatic improvement in co-morbidities such as elevated blood pressure, hyperglycemia, and lipid disorder. The best objective measure of obesity is the body mass index (BMI), which is calculated using height and weight (tables for calculating BMI are now readily available). A BMI of 27 or greater indicates obesity.

Greatly reducing the fat content of the diet is often successful in treating obesity. Vegetarian diets alone may not be successful if they contain an abundance of oils. All dietary fat is high in calories (9 calories per gram), and weight loss usually occurs if calories from fat make up less than 20% of total calories. The nutritional approach to obesity is directed toward reducing both fat content and total calories in the diet.

Increasing physical activity is the second cornerstone of management. Heavy exercise may be dangerous for obese patients, but the addition of regular physical activity, such as walking, to the daily routine fosters weight loss. Both the dietary and physical activity components of the treatment must be incorporated into the patient's lifestyle for long-term success. Behavior modification is focused on the long term rather than temporary changes.

Pharmacotherapy for the obese has entered mainstream therapy. Centrally acting drugs focusing on the neurotransmitters norepinephrine and serotonin and avoiding the dopinergic effects of amphetamines have been found to be relatively safe and effective. A combination of phentermine, a norepinephrine-releasing agent, and fenfluramine, a serotonin-releasing agent and reuptake inhibitor, has become popular. Concerns about an increase in primary pulmonary hypertension and, more recently, cardiac valvular defects have raised important questions regarding the long-term safety of these drugs. New agents, such as sibutramine, which is not a releasing agent but rather a norepinephrine- and serotonin- reuptake inhibitor, may be safer. Other therapeutic agents, such as Orlistat, which act directly on the intestine to reduce the absorption of fat, provide an alternative approach to therapy.

If we accept the serious morbidity of obesity, long-term therapy including drugs, if necessary, should be considered standard medical therapy. Currently, many health plans do not cover antiobesity treatment. This is partly due to the popularity of such treatment for cosmetic concerns. It is important that all of medicine recognize the seriousness of obesity and accept the importance of therapy. Using the BMI as a diagnostic standard should clarify those persons who require therapy. Just like hypertension, hyperlipidemia, and type 2 diabetes, obesity is a chronic disease and must be aggressively managed.

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Antiretroviral Therapy: An Update

PRABASHNI REDDY, PHARM.D. AND JACK ROSS, M.D.

THE treatment of human immunodeficiency virus (HIV) infection is a rapidly changing arena. Treatment guidelines published in *JAMA* in 1996 have been recently updated.[1,2] In addition, the National Institutes of Health (NIH) released a draft proposal of the principles of therapy and clinical practice guidelines.[3,4] This article is a compilation of these new recommendations as practiced in adult and adolescent patients at Hartford Hospital.

A major advance in the management of HIV infected patients has been the availability of viral load or HIV RNA assays which quantify the virus in plasma. Viral load has been found to be a strong predictor of outcome with a reduction associated with a decreased risk of disease progression and death. While HIV RNA in plasma is an indicator of viral multiplication, the CD4 count signifies damage already done to the immune system. There are currently two available assays to measure viral load, namely, RT-PCR (reverse transcriptase polymerase chain reaction) and the bDNA (branched DNA). The former tends to provide results twice the level of the latter test. However, it is recommended that the same assay be used consistently as this correction factor is not always accurate.[3,4]

The time to start therapy is controversial. Advocates of early therapy aim to control replication and mutation, hence reducing the potential for drug resistance. In turn, a decline in immune status may be prevented, thus delaying the progression to AIDS. Furthermore, drug toxicity may be minimized if therapy is commenced during the initial course of infection. However, once therapy is started, the quality of life may be impaired because of adverse effects of the drugs. In addition, resistance may develop early leading to the risk of dissemination of a mutant virus, thus limiting future drug options.[4]

The decision to start or change therapy is based on five factors, namely: viral load, CD4 counts, clinical progression of the disease, as well as patient willingness to commence therapy and adhere to treatment.[2-4]

Therapy has been *recommended* in the following group of patients:

- symptomatic HIV disease, regardless of CD4 count or viral load
- viral load >5,000 to 10,000 copies/mL, regardless of CD4 count (*JAMA*)
- viral load >10,000 (bDNA) or >20,000 copies/mL (RT-PCR) (NIH)
- CD4 <500/μL (especially less than 350/μL) (*JAMA* and NIH)

Therapy should be *considered* if:

- HIV levels are detectable in plasma (*JAMA*)
- CD4 >500/μL and HIV <10,000 to 20,000 copies/mL (NIH)

If the decision is made not to initiate therapy, the viral load should be measured every three to four months while the CD4 count should be monitored every three to six months (NIH).

Drug Therapy

If drug therapy is to be commenced, expert consultation is recommended as the management may be complex. The immense cost of these agents needs to be considered as the cost of regimen 1 may vary from $10,910 to $14,310 per year, while regimen 2 may cost from $7,910 to $9,030 per annum. Moreover, patients may be receiving drug therapy for associated conditions which further add to the cost of treating this disease.[5]

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Three major classes of antiretroviral drugs are available; nucleoside reverse transcriptase inhibitors (NRTI), protease inhibitors (PI), and non-nucleoside reverse transcriptase inhibitors (NNRTI). The dosing recommendations and side effects of the former two groups are summarized in Tables 1 and 2. As protease inhibitors are potent inhibitors of the cytochrome p450 3A system, especially ritonavir, this class of agents has the potential for multiple drug interactions. Furthermore, protease inhibitors are metabolized by the cytochrome p450 system, hence enzyme inducers may reduce the levels of the antiretroviral agent. This is of particular relevance in patients receiving concomitant rifampin-containing antituberculosis regimens. Guidelines regarding the management of these patients have been published.[6] Thus, if patients are receiving protease inhibitors, prescribers should *always* check for the possibility of drug interactions.[4]

Nevirapine (Viramune®) and delavaridine (Rescriptor®) are the two marketed NNRTIs. These drugs are well tolerated, with the chief complaint being rash in most patients. Cross resistance between the drugs does occur.[4] Drug interactions may occur as nevirapine induces the cytochrome p4S0 3A system while delaviridine inhibits the 3A and 2C9 enzymes.[4,7]

Drug Regimens

The goal of treatment is to maintain HIV RNA levels below the limits of detection.[4] Combination therapy has been clearly shown to be superior to monotherapy with triple drug regimens being the most potent. These regimens include two NRTIs plus either a PI or NNRTI. Regimens 1 and 2 (Table 3) have been recommended by the NIH while the remaining combinations may be less effective alternatives.

Regimen 1—Two nucleoside reverse transcriptase inhibitors + one protease inhibitor.—A protease inhibitor from column two is combined with any double NRTI combination listed in column 1. Patient adherence is crucial otherwise resistance will develop rapidly to the protease inhibitor. Unfortunately, the durability, long-term tolerance, and overall benefit in naive patients with early disease is unknown.

Regimen 2—Two nucleoside reverse transcriptase inhibitors + one non-nucleoside reverse transcriptase inhibitor.—Two NRTIs as listed in Table 3 are combined with an NNRTI. This regimen may decrease HIV RNA levels below assay limits and is most successful in patients naive to the chosen NRTIs. Some experts have considered this combination equivalent in efficacy to regimen 1.

Regimen 3—Two nucleoside reverse transcriptase inhibitors.—A double NRTI regimen is less effective than regimen 1 or 2. However, it is preferable to no treatment in patients at high risk of disease progression. This option may be considered when regimens 1 and 2 are not possible because of cost or likely nonadherance to therapy. Frequent monitoring is recommended, with any evidence of disease progression necessitating more aggressive therapy.

4. Other combinations.—The combination of ritonavir and saquinavir appears promising in early trials. The efficacy of NRTI + NNRTI + PI and four-drug regimens

Table 1.—Nucleoside reverse transcriptase inhibitors[4,8-12]

Generic	**Didanosine†**	**Lamivudine†**	**Stavudine†**	**Zalcitabine†**	**Zidovudine**
Abbreviation	ddl	3TC	d4T	ddC	ZDV, AZT
Trade name	Videx	Epivir	Zertit	Hivid	Retrovir
Dose	>60kg: 200mg bid <60kg: 125mg bid	150mg bid	>60kg: 40 mg bid <60kg: 30mg bid	0.75mg tid	200mg tid or 300mg bid
Administration	two tablets must be administered to provide adequate buffering; 30 minute before meals	+/– food	+/– food	14% decrease in bioavailability with food	+/– food
Side effects	Pancreatitis Peripheral neuropathy Nausea Diarrhea	GI toxicity Fatigue Headache	Peripheral neuropathy Increased liver enzymes Macrocytosis	Peripheral neuropathy Stomatitis Pancreatitis	Bone marrow suppression GI side effects Headache Myopathy Hepatitis

†Dosage adjustment in renal impairment required.

eg, ritonavir, saquinavir, d4T, and 3TC are currently unknown although clinical trials are in progress. The following regimens should be avoided based on experimental evidence: all monotherapies, d4T+ZDV, ddC+ddl, and ddC+3TC.

Monitoring

Following commencement of therapy a fall in viral load is typically observed within two to four weeks although up to 12 to 24 weeks of treatment may be required before maximal suppression is seen. HIV RNA levels should not be measured during or within four weeks after treatment of an intercurrent infection or immunization as these results are not a reliable indicator of viral multiplication.[4]

Changing Therapy

The need to alter a regimen may arise in several situations. There are five reasons for considering a change in therapy.[2,4]

- Toxicity
- Intolerance
- Nonadherance
- Treatment failure
- Suboptimal regimens

If drug toxicity or intolerance arises, the drug may be replaced with an agent with a different side effect profile. Lowering the dose of a protease inhibitor as a means of reducing side effects should be avoided as resistance to the drug may rapidly develop. If nonadherance arises during therapy, patients may be re-commenced on the previous regimen. However, patients would then require monitoring to assess continued response to the regimen. Treatment failure is evidenced by viral loads of 2,000 to 5,000 copies/mL in patients who had previously been maximally suppressed or an increase by 5,000 to 10,000 copies/mL in patients whose HIV RNA was always above the limits of detection. Suboptimal regimens include monotherapy or a combination of two NRTIs alone. Before a change in therapy is made, intercurrent illness and vaccinations as possible reasons for the apparent treatment failure need to be evaluated. Expert opinion should be obtained when viral load increases with an unchanged CD4 count and when both viral load and CD4 count decline. The NIH recommendations for therapeutic changes, based on the initial regimen, are presented below.

1. *Two NRTIs + PI.*—The two NRTIs should be replaced with two new NRTIs. The initial protease inhibitor as listed below in column 1, should be substituted with drug(s) as shown in column 2.

Initial regimen	New regimen
Nelfinavir	Ritonavir, indinavir, saquinavir+ritonavir, nevirapine+ritonavir or nevirapine+indinavir
Ritonavir	Saquinavir+ritonavir, nelfinavir+nevirapine
Indinavir	Saquinavir+ritonavir, nelfinavir+nevi rapirapine
Saquinavir	Nelfinavir, ritonavir, saquinavir+ritonavir, nevirapine+indinavir

Table 2.—Protease inhibitors[4,13]

Generic	Indinavir	Nelfinavir	Ritonavir	Saquinavir
Trade name	Crixivan	Viracept	Norvir	Invirase
*Dose**	88mg q8h	750mg q8h	600mg q12h**	600mg q8h
Administration	One hour before or after meals or with low-fat meal	with food	with food	with high fat meal
Bioavailabiltiy (%)	30	20–80	unknown	Four (capsule)
Metabolism	p450 cytochrome 3A4	p450 cytochrome 3A4	p450 cytochrome 3A4, 2D6, 2C9/10	p450 cytochrome 3A4
Side effects	GI intolerance Nephrolithiasis ↑ Bilirubin and liver enzymes Headache Insomnia Hyperglycemia	GI intolerance Asthenia Headache ↑ BP (moderate) Hyperglycemia	GI intolerance Parasthesias Taste alteration ↑ Triglycerides ↑ CPK ↑ Transaminases ↑ Uric acid Fatigue Hyperglycemia	GI intolerance Headache ↑ Transaminases Hyperglycemia

*Insufficient information regarding dosage adjustment in renal impairment. **Titrate over two to three weeks.

2. Two NRTis + nevirapine.—Replaced with two new NRTIs and a protease inhibitor.

Patients receiving one or two NRTIs should be commenced on regimens 1 or 2 as listed in Table 3.

Conclusion

Considerable progress has been made in recent years in the treatment of HIV infections. In particular, the addition of protease inhibitors to the drug armamentarium has enabled viral load to be suppressed to undetectable levels. Several new protease inhibitors are undergoing clinical investigation while an additional non-nucleoside reverse transcriptase inhibitor is under development.[14,15] As the management of these patients is complex, expert consultation is a necessity. While this synopsis has attempted to summarize current treatment recommendations, readers should take note of any new developments, as the treatment of HIV infections is in an evolutionary stage.

Regimens	NRTIs	PI	NNRTIs
1. Two NRTIs + PI	ZDV + ddl ZDV + 3TC ZDV + ddC d4T + 3TC d4T + ddl	Indinavir Nelfinavir Ritonavir Saquinavir*	—
2. Two NRTIs + NNRTI	As Above	—	Delavaridine Nevirapine
3. Two NRTIs	As Above	—	—

*Evidence of lower efficacy

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Outbreak of Staphylococcal Food Poisoning Associated with Precooked Ham—Florida, 1997

On 27 September 1997, a community hospital in northeastern Florida notified the St. Johns County Health Department about several persons who were treated in the emergency department because of gastrointestinal illnesses suspected of being associated with a common meal. This report summarizes the investigation of the outbreak by the Florida Department of Health; the findings implicated staphylococcal intoxication as the cause of illness among some persons who attended a retirement party on 26 September 1997.

Self-administered questionnaires were distributed to the 125 attendees to document food histories, illnesses, and symptoms. A case was defined as nausea and/or vomiting in a person who attended the party or consumed food served at the party and who became ill within eight hours after eating. Leftover food was collected and submitted for laboratory analysis. Food preparers were interviewed about the purchase and preparation of food served at the party.

Of the approximately 125 persons who attended the party, 98 completed and returned questionnaires. Of these, 31 persons attended the event but ate nothing, and none of them became ill; they were excluded from further analysis. A total of 18 (19%) persons had illnesses meeting the case definition, including 17 party attendees and one person who ate food brought home from the party. Ill persons reported nausea (94%), vomiting (89%), diarrhea (72%), weakness (67%), sweating (61%), chills (44%), fatigue (39%), myalgia (28%), headache (11%), and fever (11%). Onset of illness occurred at a mean of 3.4 hours after eating (range: 1-7 hours); symptoms lasted a median of 24 hours (range: 2-72 hours). Seven persons sought medical treatment, and two of those were hospitalized overnight. Illness was strongly associated with eating ham (risk ratio=26.8 [95% confidence interval=3.8-189.6]). Of the 18 ill persons, 17 (94%) had eaten ham. The ill person who had not attended the party had eaten only leftover ham. None of the other foods served at the party were significantly associated with illness (Table 1).

One sample of leftover cooked ham and one sample of leftover rice pilaf were analyzed by reversed passive latex agglutination to identify staphylococcal enterotoxin and were positive for staphylococcal enterotoxin type A. Samples of stool or vomitus were not obtained from any ill persons, and cultures from nares or skin were not obtained from the food preparers.

On 25 September, a food preparer had purchased a 16 pound precooked packaged ham, baked it at home at 400º F (204º C) for 1.5 hours, and transported it to her workplace, a large institutional kitchen, where she sliced the ham while it was hot on a commercial slicer. The food preparer reported having no cuts, sores, or infected wounds on her hands. She reported that she routinely cleaned the slicer in place rather than dismantling it and cleaning it according to recommended procedures and that she did not use an approved sanitizer. All 16 pounds of sliced ham had been placed in a 14-inch by 12-inch by 3-inch plastic container that was covered with foil and stored in a walk-in cooler for six hours, then transported back to the preparer's home and refrigerated overnight. The ham was served cold at the party the next day. The rice pilaf was prepared the day of the party by a different person.

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Editorial Note: Staphylococcal food poisoning, caused by enterotoxin-producing strains of *Staphylococcus aureus, is* one of the most common foodborne illnesses.[1] Sudden onset of nausea, vomiting, and diarrhea usually occurs 30 minutes to eight hours after eating contaminated food; the incubation period may vary in relation to individual susceptibility, amount of toxin in the food, and amount of food ingested. Although the duration of illness is short and almost always self-limited, some deaths have been reported.[2]

Reprinted from the *Morbidity and Mortality Weekly Report*. 19 December 1997; vol. 46, no. 50, Centers for Disease Control (CDC), National Institute for Health (NIH).

Table 1.—Attack rates and risk ratios associated with buffet foods, by food type— Florida, September 26,1997

Food	Attack rate (%)		Risk ratio	(95% CI*)
	Ate	Did not eat		
Ham	65.4	2.4	26.8	(3.8–189.6)
Chicken	30.0	25.5	1.2	(0.5–2.7)
Turkey	38.9	22.4	1.7	(0.8–3.8)
Rice pilaf	15.4	29.6	0.5	(0.1–2.0)
Rolls	47.1	20.0	1.4†	(0.8–2.3)
Eggs	34.8	22.7	1.5	(0.7–3.3)
Salad platter	31.3	25.5	1.2	(0.5–2.9)
Nuts	25.0	27.1	0.9	(0.3–3.3)
Cake	23.5	28.0	0.8	(0.3–2.2)
Cookies	11.8	32.0	0.4	(0.1–1.4)
Punch	18.4	37.9	0.5	(0.2–1.1)

*Confidence interval.
†Summary risk ratio after stratifying on ham consumption.

Although staphylococci are commonly found on environmental surfaces and in a wide variety of mammals and birds, humans are thought to be the primary source of organisms associated with staphylococcal food contamination. Organisms may be present in the nasal passages, throat, hair, and skin of healthy persons, and are abundant in cuts, pustules, and abscesses.[2,3] Staphylococci grow in the temperature range of 45º F and 118º F (7º C and 48º C); rapid growth and enterotoxin production occurs between 68º F and 99º F (20º C and 37º C). Although growth usually is constrained by the presence of competing organisms, staphylococci thrive in high concentrations of salt and sugar that other organisms cannot tolerate. Staphylococcal enterotoxins are highly resistant to heat. Measures to prevent the growth of *S. aureus* are critical because normal temperatures used in cooking will not destroy the toxins, and foods containing staphylococcal enterotoxin usually look and taste normal.[2,3]

Ham is the most commonly reported vehicle of transmission in staphylococcal food poisoning.[1,4] The salt content of precooked, packaged hams is high, often as high as 3.5%, which provides an ideal growth medium for *Staphylococcus*.[2] Although the exact source of contamination for the ham in this outbreak is unknown, the ham could have been contaminated by the food preparer's hands, even though she had no signs of staphylococcal infection. Only one third of food handlers from whom staphylococci are isolated have symptoms consistent with an active staphylococcal infection.[4] The ham also could have been contaminated by contact with the slicer because the slicer had not been cleaned adequately. Slicing the ham when the ham was warm increased the surface area and provided a favorable temperature for replication of toxin-producing organisms. In addition, placement of a large quantity of warm, salty ham in a small, tightly closed container prevented rapid cooling and extended the time during which growth and toxin production occurred.

To reduce the incidence of staphylococcal gastroenteritis, potentially hazardous foods such as baked ham must be prepared and served appropriately. The amount of manual handling should be minimal, and food preparers should wash their hands thoroughly before handling food. Food contact surfaces and equipment such as slicers should be cleaned and sanitized. Ham should be sliced cold or, if served warm, immediately before serving to decrease the opportunity for replication of organisms introduced during slicing. Food should be eaten promptly after cooking or refrigerated immediately at a temperature <41º F (<5º C). To permit rapid cooling, food should be stored in small portions in containers that are shallow and loosely covered; this method facilitates adequate air flow and rapid transfer of heat from the food to the container.[5]

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THE MEDICAL LETTER

St. John's Wort

MANY readers have asked the *Medical Letter* to evaluate St. John's wort, an herbal extract now widely sold in health food stores and pharmacies, for its effectiveness and safety in the treatment of depression. St. John's wort is licensed in Germany for treatment of anxiety, depression and insomnia. In the U.S.A., it is considered a dietary supplement and has not been evaluated by the FDA.

INGREDIENTS—"St. John's wort" is a common name for the flowering plant *Hypericum perforatum* (Upton R., ed, *St. John's Wort,* Santa Cruz, CA: American Herbal Pharmacopoeia, July 1997). It has many constituents with biological activity, including naphthodianthrones, flavonoids, phloroglucinols and xanthones. Hypericin, a naphthodianthrone, is generally considered the active ingredient, and in Germany dosage of the herb is based on its hypericin content. The amount of hypericin varies widely in different parts of the plant, under different growth conditions and at different times of the year.

PHARMACOLOGY—Hypericum extract inhibits uptake of the neurotransmitters serotonin, norepinephrine and dopamine and binds to GABA receptors *in vitro,* but whether it crosses the blood-brain barrier is unknown. Some constituents of the plant inhibit monoamine oxidase (MAO), but their concentration in extracts appears to be low. With oral administration of an extract, serum concentrations of hypericin reach a peak in about five hours and a steady state in about four days. Whether it is metabolized and how it is excreted are unknown. The half-life of hypericin in plasma is about 25 hours (Staffeldt B, et al, *J Geriatr Psychiatry Neurol,* 1994; 7 suppl 1:S47).

CLINICAL TRIALS—A meta-analysis of 23 randomized trials in a total of 1,757 outpatients with mild or moderate depression found hypericum extracts, after two to four weeks, superior to placebo and about as effective as standard antidepressants (Linde K, et al, *BMJ*, 1996; 313:253). However, in most of these studies the diagnosis of depression was not well established, the placebo response rate was lower than usually seen in such studies, the dosage of standard antidepressants was low, and the dosage of hypericin varied more than six-fold. One study lasted 12 weeks, three lasted eight weeks, one lasted only two weeks and the rest had a duration of four to six weeks.

ADVERSE EFFECTS—No serious adverse effects have been reported with use of St. John's wort. Some patients have complained of dry mouth, dizziness, constipation, other gastrointestinal symptoms and confusion. In trials, fewer than 2% of patients stopped taking the herb because of adverse effects. The plant has caused severe contact photosensitivity, grazing animals have had phototoxic reactions after eating it, and systemic photosensitivity has been reported in one patient taking an extract for depression (Golsch S, et al, *Hautarzt*, 1997; 48:249).

CONCLUSION—Better, longer studies are needed to establish the effectiveness and safety of St. John's wort for treatment of depression. The active ingredients, the potency and the purity of the preparations sold in the USA are all unknown.

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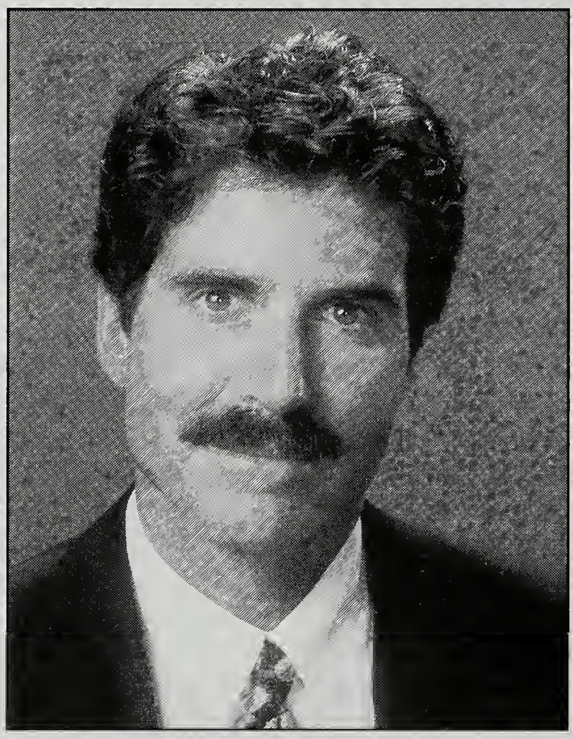
Stuttering Didn't Silence His Story.



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Connecticut State Special Olympics: Observations and Recommendations

HAROLD J. GALENA, M.D., CHARLES R. EPSTEIN, E.M.S.I.,
AND RITA J. LOURIE, M.S.N.

ABSTRACT: The Connecticut State Special Olympics provides an opportunity for thousands of developmentally challenged children and adults to participate in athletic events. This paper retrospectively reviews the demographics and documentation of medical problems in 1994, 1995, and 1996 Summer Games. The 1994 and 1995 summer games took place at the Coast Guard Academy and Connecticut College in New London. The 1996 summer games occurred at Fairfield and Sacred Heart Universities in Fairfield. The mean age of the participants ranged from 30 to 32 years of age. Minor trauma made up the largest percentage of encounters. Most of these injuries were sprains or strains to the lower extremities. The more serious injuries included dislocations and fractures. The incidence of seizure remained stable over these years. A comparison of the 1994, 1995, and 1996 games revealed a nearly 600 fold increase in heat-related dehydration in Fairfield as compared to the 1994 and 1995 games in New London. The highest incidence of sunburn occurred in 1995 despite the availability of sunblock. A concerted effort to reduce sunburn in the 1996 games in Fairfield resulted in a marked decrease of sunburn despite the higher temperatures, but an increase in chemical irritation to the eyes. Recommendations are presented to decrease the incidence of medical problems.

Introduction

THE Connecticut State Special Olympics Program has developed and grown over recent years and includes some 3,500 potential participants. The major criterion for participation has been mental retardation. While the definition of mental retardation remains an issue, the definition used is intellectual functioning level (IQ <75); significant limitations in two or more adaptive skill areas; and the condition manifesting itself before the age of 18.[1] Approximately 2.5% to 3% of the population in the United States is mentally retarded. Persons are eligible for Special Olympics providing they are five years old or older, have been identified by an agency or professional as having mental retardation, have cognitive delay as determined by standard measures, or have significant learning or vocational problems due to cognitive delay that require specially designed instruction.[2] Often the mentally retarded have other physical disabilities such as impaired hearing, vision, coordination, or musculoskeletal deficiencies.[3,4] A medical examination is required by all participants prior to their participation.

The current policy for the Special Olympics is to utilize one site for three consecutive years, eg, the summer games in New London occurred in 1993, 1994, 1995 and the 1996 summer games were in Fairfield and will be there again in 1997 and 1998. This allows for preparation and improvement in the same location.

The medical team for the Special Olympics has included medical personnel volunteers including physicians, EMTs, and registered nurses. Both the New London and Fairfield sites had personnel on the field at designated medical tents with medical first aid, ambulances, and golf carts. An infirmary was provided at both the Coast Guard and at Fairfield University. The present study retrospec-

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Table 1.—Mean age of participants for the 1994, 1995, and 1996 Connecticut Special Olympics Summer Games and the general pool of all Special Olympian Athletes.

<table>
<tr><th>1994</th><th>1995</th><th>1996</th><th>General pool of all registered potential participants</th></tr>
<tr><td>30.1
SD = ± 11.3
N = 100</td><td>31.3
SD = ± 12.9
N = 100</td><td>30.8
SD = ± 12.8
N = 100</td><td>32.9
SD = ± 11.3
N = 100</td></tr>
<tr><td colspan="4">The mean age in the general pool is higher than the actual participating years probably reflecting aging of the files over the past 10 years. There approximately 3,500 potential participants in the general pool.</td></tr>
<tr><td colspan="4">Mentally challenged or seizure disorder in the general pool of participants as recognized by their personal M.D. from the physical examination form completed prior to participation.</td></tr>
<tr><td colspan="2">Seizure disorder</td><td>20</td><td></td></tr>
<tr><td colspan="2">Down's syndrome/ Trisomy 21.</td><td>13</td><td></td></tr>
<tr><td colspan="2">Cerebral palsy</td><td>1</td><td></td></tr>
<tr><td colspan="2">Traumatic brain injury</td><td>6</td><td></td></tr>
<tr><td colspan="4">The above data are obtained from a pool of 100 participants.</td></tr>
<tr><td colspan="4">Mentally challenged disorders are most often genetic in origin and are stable. The etiology of the mental impairment is often unknown though there has been more interest in identifying the genetic defect by chromosome testing. Down's syndrome is the most well known of all and affects one in 500–600 births. Also, the syndrome of fragile X has been identified as one of the common causes of mental retardation(1). There were none identified from the pool of physical examination sheets.</td></tr>
</table>

tively reviewed the medical encounters of the 1994, 1995, and 1996 Connecticut State Summer Games.

Methods

Medical Records were reviewed by a physician for the following information: encounter diagnosis, medications, vital signs, disposition, and treatment. The weather for each day of the games was obtained through the Connecticut Weather Service in Danbury, Connecticut (Table 6). Demographics of the participants was obtained from the National Special Olympics office in Washington, DC.

Results

The mean age of the participants (Table 1) was 30.1 in 1994, 31.3 in 1995, and 30.8 in 1996 with an age range of eight to 77 with essentially an equal male to female ratio.

A total of 674 incidents were reviewed from 1994, 1995, 1996 (Table 2). Trauma-related injuries made up 375 incidents or 56% of the total. Sprains, contusions, and abrasions made up the bulk of the trauma-related encounters (Table 3). Sunburn constituted 33 incidences, representing 8.8 % of the total trauma incidences with the worst year for sunburn being 1995. Though sun block was available in 1995, a more aggressive team approach in 1996 resulted in less sun burning (only five incidents or 3.6% of the incidents in 1996) but more chemical irritation to the eyes in 1996 (20 incidents or 14.3%). Only two fractures were reported in the three years: a tibial plateau fracture and a radial head fracture. While there were numerous contusions and sprains, there was remarkably little severe head or neck injury. Most sprains and contusions were to the lower extremities (Table 4). Heat exhaustion represented the largest percentage of medical encounters in 1996 (Table 5).

Table 2.—Trauma and medical incidents at the Connecticut Special Olympics Summer Games: 1994, 1995, and 1996:

A comparison between the Connecticut Summer Olympics at New London and Fairfield, and the 1995 International Special Olympics at New Haven, Connecticut.

Connecticut State Summer Games					International World Games *
	1994	1995	1996	Total	1995
Total	186	220	268	674	1,491
Trauma	102	133	140	375 (57.3%)	807 (54.2%)
Medical	84	80	115	279 (42.7%)	684 (45.8%)

*Data on the International World Games was obtained from a thesis on the International World Games.[2]

Table 3.—Medical incidents (nontrauma) at the Connecticut Special Olympics Summer Games: 1994, 1995, and 1996

Medical	**1994**	**1995**	**1996**
Heat exhaustion	8	11	57
Seizures	7	8	8
Headache	4	3	4
Chest pain/cardiac	4	0	7
Cellulitis/abscess	2	2	5
Asthama/bronchitis	4	6	4
Dermatitis	5	8	9
Diabetes	6	5	6
Urinary infection	0	3	1
Psych/anxiety/panic	4	1	1
Suicide attempt	0	1	0
Hypertension	2	1	0
Allergy	1	3	0
Syncope/dizziness	4	1	0
Impacted ear wax	0	2	0
Upper respiratory infection/flu	5	1	0
Insect bites/stings	11	2	0
Hypothermia	0	3	0
Nosebleeds	2	0	0
Abdominal pain	8	9	8
Stye	0	0	1
Dental/toothache	0	2	0
Medicine delivery	4	6	0
Plantar wart	0	0	1
Wound care	0	2	0
Aspiration/choking	1	0	3
	84	**80**	**115**

Intravenous fluids and other aggressive care included patients with chest pain, congestive heart failure, palpitations or arrhythmias, acute asthmatic attacks, a suicide attempt, recurrent or persistent seizure activity, and abdominal pain with vomiting. Seven episodes of seizures were reported in 1994, eight in 1995, and eight in 1996 (Table 5). All except one had a documented history of seizures and were on seizure medications. Insect stings or bites were highest in 1994. Infections of the urinary tract and skin were the most common infections noted. Several had ingrown toe nails with local cellulitis. Blisters were also very common.

Discussion

The percentage of trauma *vs* medical encounters reported during the 1994, 1995, and 1996 Connecticut State Special Olympic Summer Games was similar to that seen in the 1995 World Games in New Haven (Table 2). Except for an unusually high number of insect bites and stings in 1994 and a high incidence of sunburn in 1995, the 1994 and 1995 Connecticut Special Olympics presented similar medical problems. Insect bites and stings are unpredictable. Sunburn is predictable especially when some of the events occurred at the beach. Sunblock was available but apparently underutilized. Also, several events were at Ocean Beach, and the intensity of the sun's rays reflection from the water may have been a contributing factor even though the day was not exceptionally warm.

Recommendations

Water was readily available but dehydration is a constant concern. Getting athletes to drink was difficult. Many of the Special Olympians are taking medication, such as antiseizure and psychotropic drugs, that affect their desire to drink. Coaches must insist that participants drink adequately and provide refreshing drinks. Adequate shade with tents in open areas and loose clothing are imperative.[5] Efforts to supply a strong sunblock which will not be irritating to the eyes must continue and protective hats must be provided. During the 1995 games there were 11 cases of heat exhaustion of which eight occurred

Table 4.—Injuries (contusions and sprains) at the Connecticut Special Olympics Summer Games:

	1994	**1995**	**1996**	**Total**
Head and neck	7	7	5	19 (12.4%)
Upper extremity	10	9	10	29 (18.9%)
Chest	2	2	3	7 (4.5%)
Lower extremity	35	32	36	103 (67.3%)
Total	**54**	**50**	**54**	**153**

Table 5.—Heat-related illness (dehydration and heat exhaustion) and seizures during the 1994, 1995, and 1996 Connecticut Special Olympics Summer Games at New London and Fairfield. A comparison between these Connecticut State Summer Games and the 1995 International World Games in New Haven, Connecticut.

	Connecticut State Summer Games			International World Games
	1994	1995	1996	1995
Heat-related illness	8	11	57 = 76 (11.27%)	112 (7.7%)
Seizures	7	8	8 = 23 (3.41%)	56 (3.71%)

The Connecticut State Special Olympics occurred over a three-day weekend in 1994, 1995, and 1996, a total of nine days. The International World Special Olympics occurred over a nine-day period in 1995. A comparison is made of the total of the nine days during the three years and the nine-day International Special Olympics. Heat-related illness was more during the International World Special Olympics than at the total of the three weekends of the Connecticut State Games. The mean T for the 1994, 1995, and 1996 summer games was lower (mean T = 64.5) as well as the heat index (74.7).

The weather during the 1996 Connecticut State Special Olympics was significantly hotter (mean T = 69.9) and more humid with a mean heat index of 81 (see Table 3). This resulted in a dramatic increase in heat-related illness as compared to the 1994, and 1995 summer games.

The incidence of seizures remained stable and was between 3% to 4% of all encounters.

in the evening at the dance. Efforts must be made to provide for proper space and proper ventilation for this yearly event.[6] Scheduling the more vigorous outdoor events in the morning would avoid the heat intensity of the day while scheduling the swimming events in the afternoon. The State Special Olympics take place in early June which is usually the coolest time of the summer and this should continue. Heat-related illness, while always a concern, has been less in recent years because of cooler temperatures and the location in New London, a coastal city that is not only cooler but has the advantage of the ocean. Interestingly, of the 112 who were treated for heat exhaustion or dehydration only four were treated at Yale-New Haven Hospital. Every Special Olympics site should have an adequate supply of intravenous fluid to avoid hospitalizations.

Abdominal pain associated with nausea and vomiting was also a common complaint. Appropriate dietary choices such as low fat, complex carbohydrate meal rather than a high fat, meat meal should be the dietary choice prior to the event. Coaches should be cautioned by medical personnel to limit the amounts of food the athletes consume prior to their event.

Conclusion

The Connecticut Special Summer Olympics offers developmentally challenged residents an opportunity to socialize and compete in a controlled and supportive environment. It is the responsiblity of the medical profession to make this experience as safe as possible by reducing the incidence of medically related occurrences through primary prevention, careful assessment of risk factors, and meticulous planning.[7]

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Table 6.—Air temperature, dewpoint, relative humidity, and heat index during the 1994, 1995, and 1996 Connecticut Special Olympics at New London and Fairfield and the 1995 International Special World Olympics at New Haven.

Date	Air Temperature	Dewpoint	Mean	Relative Humidity	Heat Index
Connecticut Special Olympics: New London, Connecticut					
6/10/94	High: 73º Low: 53º	50º	63	44%	70
6/11/94	High: 70º Low: 49º	59º	59.5	68%	70
6/12/94	High: 68º Low: 60º	64º	64	87%	N/A
Mean		56.66º	62	66.33%	70
6/9/95	High: 72º Low: 56º	54º	64	53%	70
6/10/95	High: 72º Low: 52º	56º	62	57%	72
6/11/95	High: 64º Low: 56º	60º	60	87%	N/A
Mean		62º	62	65.66%	71
Connecticut Special Olympics—Fairfield, Connecticut					
6/7/96	High: 75º Low: 59º	60º	67	59%	77
6/8/96	High: 81º Low: 62º	70º	71.5	69%	89
6/9/96	High: 76º Low: 65º	68º	70.5	76%	77
Mean		68.66º	T = 69.66	68%	81
Mean of all three events		64.22º	64.55	66.66%	74
International Special Olympics—New Haven, Connecticut					
7/1/95	High: 81º Low: 68º	68º	74.5	64%	68
7/2/95	High: 79º Low: 63º	58º	71	48%	80
7/3/95	High: 78º Low: 55º	53º	66.5	41%	78
7/4/95	High: 84º Low: 59º	58º	71.5	41%	84
7/5/95	High: 81º Low: 64º	58º	72.5	45%	81
7/6/95	High: 85º Low: 67º	64º	76	49%	88
7/7/95	High: 83º Low: 69º	67º	76	58%	87
7/8/95	High: 85º Low: 65º	69º	73	58%	90
7/9/95	High: 76º Low: 57º	57º	66.5	51%	77
Mean		61.33º	T=71.9	50.55%	83.44

The above are the air temperatures, dewpoints, mean temperatures, relative humidity, and calculated heat index. For the calculations, the highest temperature of the day was chosen along with its associated dewpoint temperature recorded at that time. From data the relative humidity was computed which then was used to utilize the heat index equation. The definition of heat index is the air temperature when combined with the relative humidity, we obtain an apparent air temperature. For example, when a given temperature is combined with humid conditions we obtain a temperature which feels hotter (Connecticut Weather Center, Danbury, Connecticut).

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Research Promotion Between Managed Care Organizations and Healthcare Delivery Systems

MARIA LENAZ, M.D.

ABSTRACT—Research ventures between health maintenance organizations and academic medical centers can prove mutually beneficial. The different priorities and perspectives of the two institutions with regard to health care and research may prove to be a learning process.

JOINT ventures between health maintenance organizations and academic medical centers can strengthen both organizations from the research and patient care perspectives, by facilitating the exploration of views and cost-effective approaches to diagnoses and treatment. The differing priorities and perspectives of these institutions' organizational structures require that considerable attention be paid to their representatives' working relationships and perceptions.[1]

Research faces the challenge of balancing relevance to decision making and excellence in the adherence to the norms of scientific inquiry. The complexities of health problems demand that we create new organizational formulas to balance relevance and excellence in research.[2] The criteria of good business management can also be applied to research programs, with benefit to the latter. The objectives of both are fundamentally similar; in one case to produce goods and services, in the other to produce scientific papers. The most successful goods and services, and scientific projects, are those that are closely geared to the desires of consumers, whether the latter be the general public or large organizations.[3]

Academic health centers are facing challenges with the changing environment of health-care delivery in addition to the effect of the changing health-care system on clinical research. Successful centers are initiating discussions with third-party payers and are implementing new initiatives. Attention to the infrastructure required to support the training and conduct of clinical research is essential for the future viability of medical schools.[4]

Challenges to collaboration include database development, the need for an integrated perspective, sensitivity to marketing matters, and a variety of technical and organizational barriers. To overcome these barriers, the interested groups must develop trust, recognize common ground, share risk, and communicate effectively.

Managed-care organizations, such as Kaiser Permanente, have a long history of conducting research that has affected medicine, not only for Kaiser Permanente but also in society at large. Significant research has been done in the areas of vaccination, screening, epidemiology, health education, clinical medicine, health policy and economics, and medical informatics.

At Oxford Health Plans the Oxford Health Plans Foundation was created to promote research that can improve the practice of medicine and enlighten individual consumers of health services. The Foundation was created as a catalyst for change in health care. The focus of the funding for the Foundation encompasses a broad range of health-care studies, such as: improving existing health-care delivery systems, creating new and better health-care systems, methodologies and procedures, developing outcomes data to evaluate and drive creative solutions to the problems of health-care delivery, expanding the range of health-care options offered to the public, and enlightening

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MARIA LENAZ, M.D., M.S., F.A.C.O.G., medical director, Oxford Health Plans, Trumbull; clinical assistant professor, Department of Obstetrics and Gynecology, Yale University School of Medicine, New Haven.

the general public regarding creative solutions to prevention, wellness, and health care. At Oxford the intent is that research will drive change and not simply create new information. Instruments of change need to be implemented at the appropriate levels for consumers, providers, educators, regulators, delivery systems, and health plans.

The Foundation is committed to pursuing research that: a) empowers individuals to make informed health-care decisions, b) focuses on the needs of at-risk populations, including Medicare, Medicaid, the uninsured, and the chronically ill, c) develops and support innovative programs in education to ensure implementation of best practice models, d) promotes the evaluation, application, and integration of alternative or complementary medicine practices, and e) evaluates the performance of managed care, including integrated and comprehensive health-care systems.

Assuring public and private financial support for clinical research has become an important topic on policy and industry agendas, as has the need to sort out the roles of the National Institutes of Health, academic health centers, managed-care plans, and pharmaceutical firms in backing and conducting research. This is significant not only for the future of clinical research but also for the health of the public.[5,6,7]

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Two Lives, Interlaced, End One Day Apart

HARRY YOON, *Hartford Courant* Staff Writer

IN his final years, Dr. Mervyn Little's greatest fear was that he would die before his wife, Olga, leaving her alone as her mental capacities waned.

So, the 89-year-old physician, his wife's biggest supporter through 62 years of marriage, struggled to stay alive despite losing part of a lung to a blood clot four years ago, despite losing the ability to eat and the strength to walk in the past year.

The struggle ended a week ago. Dr. Olga A.G. Little, though surprisingly healthy at 87, contracted pneumonia and died 30 November. And Dr. Mervyn H. Little—his face no longer draped in distress of recent months—died the next day.

"His mission," said their daughter, Elisabeth A. Rowlands, had been accomplished."

The Littles, who lived in Willimantic, were the symbiotic union of opposites, who, after meeting as medical students during the Depression, went on to become medical pioneers in eastern Connecticut. From marriage to death, one dared not live without the other.

Dr. Olga Little was the visionary—demonstrative, energetic, demanding—and intimidating to some. Her husband, while sharing her vision of providing psychiatric care for eastern Connecticut, was the taciturn Yankee, a financially astute man who gave their dreams some flesh.

Dr. Olga Little, the oldest daughter among eight children in a poor Russian immigrant family, established a psychiatry practice in Willimantic in the mid-1940s, alongside her husband's family medical practice.

There were virtually no psychiatrists between Hartford and Providence in those years, and it was a time when the field of psychiatry was looked on with some suspicion.

In 1954, the pair founded a nursing home, Natchaug Hospital, a novel concept at the time. They worked 12 to 14 hours a day, six days a week at the home, which later became a psychiatric treatment center.

Despite the demands of the workplace, Dr. Olga Little found the time to make Indian pudding, a favorite New England dessert of his, for her husband.

At home, or in the car, she would knit sweaters and socks for him. Though not caring herself for succotash, a dish of corn and lima beans, she prepared it for her husband, who had been raised on it. "He was her life," their daughter said.

Several years ago, as Dr. Olga Little's mental condition deteriorated because of Alzheimer's disease to the point that she could no longer cook, her husband would smooth things over by casually suggesting going out for dinner or making lunch himself at their Victorian home.

Six or seven autumns ago, Elizabeth Rowlands recalled, her father was driving his wife and daughter through Maine, and her mother was talking endlessly about the trees, repeating herself again and again.

Yet, their daughter said, "He answered every question as if it were the first time she asked it."

Dr. Olga Little moved into a nursing home in Windham Center four years ago, and her husband left Willimantic only once after that—to see his only grandson graduate from his alma mater, Wesleyan University.

"If anything happened to your mother," he would say to his daughter, "I'd never forgive myself."

HARRY YOON, staff writer, *Hartford Courant*. Reprinted with permission from the *Hartford Courant*.

Dr. Mervyn Little checked himself into his wife's nursing home, tweaking the facts of his condition to gain admittance, his daughter recalled.

Within a few weeks, Ms. Rowlands and her brother, Dr. George A. Little, returned him home, where a live-in home-care companion began helping him. He visited his wife frequently, sometimes engaging her in a game of cribbage, until his own deteriorating health confined him to bed.

Two weeks before her death, Dr. Olga Little was lying on her bed, staring out the window with an unusually pensive gaze. When her daughter Elizabeth asked what she was thinking, her mother could not explain.

"Time was running out for Dad, and she knew it," Ms. Rowlands said. But, "She knew that he wasn't going to let go. He was really, truly hanging on."

In his last months, Dr. Mervyn Little, a well-known raconteur, grew quieter. He had already made the necessary financial arrangements to see that his wife's needs would be met after his death. Yet his forehead grew more wrinkled; his frown lingered; his arms and legs twitched with agitation.

The Saturday before she died, Dr. Olga Little was admitted to Windham Community Memorial Hospital, where she had worked decades earlier.

She slipped into a coma in the afternoon and had died by 4:30 A.M. that Sunday.

Dr. George Little, who had driven from New Hampshire after getting the news, told his father, who was resting in his living room. Dr. Mervyn Little mouthed some sounds, looked off to the side, then back to his son, and went back to sleep.

Their daughter, a Michigan resident, arrived later. She noticed that her father's face had changed dramatically, as if filling out with relief.

About 4:30 A.M. the next day, their son, Dr. George Little, who was having trouble sleeping, was told by a home health aide that his father might be dead. He checked, and discovered it was true.

His father had died, just about 24 hours after his wife's death.

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50 Years Ago

From *The Connecticut State Medical Journal*

January 1948

Fifth Memorial Gift to Building Fund

The Board of Directors of the Institute of Living, the third oldest institution in America devoted to the treatment of nervous and mental disease, has contributed $2,000 to the Society's building fund.

The gift has been made as a memorial to Dr. Eli Todd, the hospital's first superintendent, and to commemorate the founding of the Institute by the State Medical Society in 1822. This is the fifth memorial gift to be received by the Trustees of the Building Fund.

Dr. Todd, the son of a New Haven merchant, was born on July 22, 1769. He achieved a brilliant record at Yale University, traveled widely, and upon his return to New Haven chose a career in medicine. He apprenticed himself to Dr. Ebenezer Beardsley of that city, who was then engaged "in the practice of the physick" and a leader in the group which founded the New Haven County Medical Association.

After his apprenticeship, Dr. Todd removed to Farmington and later to Hartford. During his association with Ebenezer Beardsley he developed an interest in organized medicine, which resulted in his founding of the Society of Medical Friends while he was a resident of Farmington. The Society of Medical Friends was a forerunner of the State Medical Society.

Dr. Todd's interest in medical organization continued throughout his life, and it was this interest which motivated his efforts to establish a hospital for the care of "insane" persons. During this period there was superstition concerning mental disease, and public indifference to its treatment. Todd was the leader in bringing the subject to open public discussion, and he aroused sympathy for the thousand unfortunates in our state who were neglected.

In 1820, in an address before the Hartford County Medical Association, he expressed his conviction that 'mental disorder is as definitely a manifestation of disease as is fever or a fracture," and bluntly declared: "It is our duty as civilized men to attack this disease."

At the State Medical Convention in 1821 he urged that a hospital be established for the treatment of the increasing number of insane persons in Connecticut. So persuasive were his arguments the convention named a commission to investigate insanity in the state. Following this study, the commission reported such conclusive findings that the State Medical Society voted every cent in its treasury to aid in the founding of such a hospital.

Spurred by this action, a campaign for funds was launched, and Dr. Todd labored to assure its success. Contributors were informed that the new institution would be named "The Retreat," that it would not be a custodial asylum, but a hospital for the treatment of those cases considered curable. The campaign was well received, and 1,700 persons contributed $19,000. Their contributions ranged from twelve and one half cents, a coin of the period, to $300, and included "a gross of New London Bilious Pills, market price $30." The City of Hartford contributed $4,000, on condition that the hospital be located in that city.

The General Assembly, in its 1822 session, granted a petition for incorporation of the new institution and appropriated $5,000 for its use. Five months later the subscribers met to organize and to choose the first directors and officers of the Hartford Retreat. Dr. Todd was unanimously elected superintendent and a Board of Medical Visitors was named. This Board has been continued and now comprise former presidents of the State Medical Society.

This historic institution, which pointed the way to modern psychiatric treatment, opened its door on April 1, 1824, and continued under Dr. Todd's guidance for a few brief years until his death in 1833. His ideas were revolutionary for those days, but were gradually accepted, and the humane treatment which he introduced replaced the tragic methods which had prevailed for centuries.

The Institute has become one of the most active hospitals of its type in the world, with 400 beds and over 800 admissions a year. Some years ago leading citizens of the state petitioned the General Assembly to recognize the services of Dr. Todd as a public benefactor, but no action was taken on this proposal. The memorial tablet to be placed in the new home of the State Medical Society will thus become the first formal recognition of the accomplishments of a noted leader in American psychiatry.

Reprinted from the *Connecticut State Medical Journal*, January 1948.

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Preaching to the Choir

I may be preaching to the choir, but the new year has begun. Perhaps there is some small time afforded for reflection. Our practices, and therefore our lives, continue to be affected by the ever more intrusive managers of medical care. Our professional memories prove to be distressingly short, at least judging from the persistent questions put to me as your president relating to the merits of membership in our medical societies and associations.

On the legislative front, this past year's activities were crowned by passage of the managed-care reform bill. Nationally this initiative is being carried forward under the banner of the patient bill of rights now adopted by politicians of both the left and the right, but originated in the house of medicine. A plan, again with roots within our organizations, dealing with the provision of medical care for our pediatric population, is actually in the implementation stage.

The legislative session begins in February but you all need to be aware that success during the actual legislative term depends to a great extent on the preparations made and ground work laid in the months preceding the convening of the House and the Senate. Our legislative committees and designated staff work throughout the year forwarding our interests as advocates of our patients' health and well-being.

Look out for this year's public awareness initiative sponsored by our legislative affairs and public relations committees. Entitled "M.D. Makes a Difference," we intend to call attention to and educate our public, our legislators, and the media in the significance of that M.D. degree we so cherish and strove so hard to attain. Complacency can no longer be afforded. So-called alternative care practitioners have had an effect on the public consciousness. We owe it to ourselves and to our patients who place their trust in us clearly to differentiate the doctors of medicine from the mere pretenders.

The Society sponsored MSO, *M.D. Advantage*, is continuing to evolve. It never hurts to emphasize that this organization was born of the perceived need to make available to every member of the medical society the broadest range of professional management services possible. This would allow any of us to choose the type of practice association best suited to our individual needs without ceding control of the management aspects of practice to third party entrepreneurs. There is certainly no intent to infringe upon practice initiatives already developing or in actual operation across the State. *M.D. Advantage* should not be viewed as a competitor to these existing physician sponsored organizations but rather as a potential resource. The Society and its leadership are committed to disadvantaging none of our membership while enhancing opportunities for all.

Remember that your membership affordes you a veritable cornucopia of opportunities and services to enhance your practice. The Society still owns CSMS/IPA. Our Physician Health Program is a model dedicated to serving and supporting our physician practitioners and at the same time safeguarding the public health. Our endorsed insurance company, CMIC, offers a full range of practice coverages and an array of practice enhancement services from physician and family support groups to office procedure assessments. The company sponsors educational programs throughout the year. Additionally, it provides support to a number of the Society's peer review and physician support activities.

Each year I take increasing pride in our Society and its membership as we meet the challenges of practice as we approach the millennium. There is though a larger view to be considered. While taking pride in our accomplishments and being confident in our ability to meet new challenges, we must acknowledge the necessity of our integration with our national organization, the AMA. Recent events, and I refer to the so-called "Sunbeam Affair," have allowed AMA naysayers an opportunity to criticize in a fashion far out of proportion to the actual event. An error in judgment was made by certain management level employees regarding product endorsement rights. Corrective action by AMA's

Board was forthcoming. New leadership is in place. The whole affair must be viewed in perspective. AMA is a large organization. It perceives its mandate as nothing less than to represent the physicians of the United States, their interests, and the interests of their patients to all interested parties, be they corporate or governmental. The AMA does a wonderful job defining our goals and forwarding our interests.

Time is precious to each of us. We must ration that which is available for study. This much I do know. The more I learn about our state organization and the AMA the more convinced I become of their vital importance to our profession's ultimate survival. Not all of us need to hold office, to sit on committees, to participate in running ancillary or related organizations. But times demand an awareness by each one of us of organized medicine's goals and opportunities and the opportunities participation afford. Ignorance may be bliss, but the result will be disaster. I hope I am not just preaching to the choir.

Stanley J. Keating, Jr., M.D.
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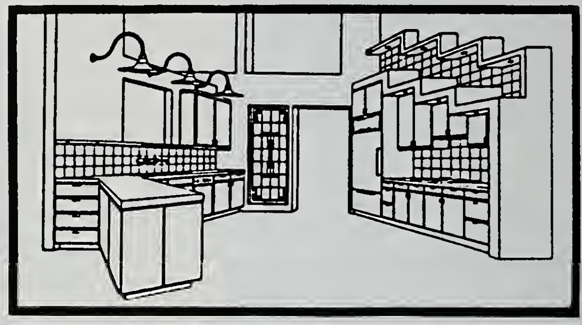

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The Kinsey Report: After 50 Years, Bogus Science

ROBERT U. MASSEY, M.D.

LATE in my residency, almost 50 years ago, I would occasionally steal away to the hospital library during a rare quiet hour to look up some abstruse point in renal tubular function or electrolyte balance, useful for scoring in the roundsmanship games in those early days of Gamblegrams and the flame photometer. More often I was just browsing.

I had read about Alfred Kinsey and his 1948 bestseller, *Sexual Behavior in the Human Male* ; one day there it was among the new acquisitions. I immediately left off thinking about potassium and milliequivalents. Nobody was watching so I tucked the book under my arm and headed for a remote corner in the stacks where I knew there was a chair and table among the dusty 19th-century bound journals.

From reviews in *Life* and *Time* I expected amazing reports of outrageous behavior among large numbers of American males. I was not disappointed. Of course, we had all read bits and pieces of Krafft-Ebing's *Psychopathia Sexualis* as undergraduates; I had dismissed it as an exaggerated account of psychopathological freaks, but here was this biologist from Indiana University, his work supported by the Rockefeller Foundation, assuring the public that all sorts of deviant behavior among boys and young men, including bestiality, was pretty much everyday stuff. I knew little and cared less about social science methodology, but had accepted that academic social scientists and social anthropologists followed the rules for disinterested scientific investigation. Furthermore the Kinsey Report, as it came to be known, seemed mostly to have been swallowed hook, line, and sinker by all those intellectuals who tell us what to think. I suppose I spent an hour or so looking mostly at his tables of data.

Kinsey simply did not square with my experience. In a large urban high school where I edited the school paper, served on the student council, dated during my senior year at least once a week, and enjoyed a fairly wide circle of friends, I knew no one who admitted to fornication or even speculated much about it; masturbation, of course, was never mentioned, and homosexuality was talked of rarely, and then only as a strange oddity. In college, a little more of this stuff came out, one or two students were expelled for misbehavior in the arboretum, and it was rumored that the music conservatory harbored a homosexual piano major. We talked of wild sexual orgies, but it was all as a joke; such things were not to be attributed to anyone any of us knew. Most of that kind of extravagant talk died out in medical school. Of course, this was wartime and perhaps we took ourselves too seriously. Anyway, in any group larger than three or four, there was always a boy scout who effectively kept the lid on. Sex talk in the presence of women was unthinkable.

After Kinsey, I came to suspect that beneath this benign surface of collegiality and mostly conventional behavior, there was in many, if not in most, a monstrous inferno of Dantean proportions. Here was Kinsey reporting a thoroughly scientific study showing that 85% of us males were fornicators, 45% adulterers, and 70% frequenters of prostitutes. The report troubled me, but I was not sophisticated enough to know that all sociological studies are biased and are simply thinly disguised propaganda for the author's political agenda. Neither, it now seems, was anyone else. There is bias in the real sciences, of course, but at least scientific data should be reproducible, capable of being proven wrong,

Proving something wrong is hard to do with studies of the Kinsey type unless it can be shown that the method was seriously flawed and the author passionately devoted to make it all come out his way. A painfully honest first-rate psychologist once told me that all psychologists, excluding himelf, of course, cook their data.

Now, after almost 50 years, a biography, *Alfred C. Kinsey, A Public/ Private Life* ,[1] has been published showing that the author of that strange report was "... a man of missionary zeal, 'a crypto-reformer who spent his every waking hour attempting to change the sexual mores ... of the United States' and who was perfectly willing to bend the canons of science to that purpose." Joseph Epstein,

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who reviewed Kinsey's biography by James T. Jones,[2] notes that "while traveling under the flag of a disinterested researcher, Kinsey himself led a secret life as a voyeur, an exhibitionist, a homosexual, and a masochist." Jones, who was the author of *Bad Blood: The Tuskagee Experiment*, treats Kinsey with the utmost sympathy, even compassion, in this biography, but leaves no doubt that the Indiana University biologist was a driven man, determined to do battle with the persisting Victorian moral code and with all the sexual repressions built into the, for him, hated Judeo-Christian religious tradition. His methods were terribly flawed, his data selection was egregiously biased. He even managed to pick his own reviewers for the scientific journals!

Sexual Behavior of the Human Female, appearing in August 1953, made a splash that was to prove short-lived. *Cosmopolitan* raved that it was "the most feverishly awaited, most widely speculated on, most sensationally publicized book in history." Kinsey even went so far as to imply that his data might not be entirely generalizable, but that was mostly unnoticed. On the day the book appeared, the Soviet Union exploded its first H-bomb; the Kinsey headlines spreading across eight columns were often bigger! But the sales did not approach the half-million expected. In spite of the overblown support by the journalistic crowd, popular enthusiasm seemed more guarded, and academicians now began to attack his methodology. The tide was turning. In Connecticut, the *Bristol Press* wrote, "If a foundation wants to lower its standards by supporting something like the questionable Kinsey research program, that is its privilege. However, when it does so and retains its tax-exempt status then the situation is of concern to every citizen."

The following summer all support for the Institute for Sexual Research at Indiana University was withdrawn by The Rockefeller Foundation. Kinsey was "thrown into a tailspin from which he never recovered."

Epstein concludes his review:

> Alfred Kinsey was a moral revolutionary in scientist's clothing. The science was bad, even bogus; the man himself may now be forgotten; but the revolution came to stay, with a vengeance. Kinsey's message—fornicate early, fornicate often, fornicate in every possible way—became the mantra of a sexridden age, our age, now desperate for a revolution of its own.
>
> At one point in this biography, Jones relates how Kinsey, in a black mood because the Rockefeller Foundation might not renew his grant, tied a rope around his scrotum, flipped the rope over a pipe, climbed onto a chair with the loose end in his hand, and jumped off, suspending himself in midair, no one knows for how long. There, hoisted by Kinsey's petard, hang we still.[2]

Jones's account of this episode (p. 739) adds, "But it was long enough for this self-appointed messiah of the sexually despised to experience much pain and suffering, precisely as he intended." Even though this story seems unbelievable, Jones has documented it fairly well; at about this time Kinsey was hospitalized for a massive "pelvic infection," which he described as being from a "strep throat."

How much Alfred Kinsey and his gospel formed the culture of the Boomer generation, and through them, their children's, only some social scientist or historian of the future can tell. Count on it, that report too will be biased.

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1. Jones JH: *Alfred C. Kinsey: A Public/Private Life*. New York: W.W.Norton & Company; 1997.
2. Epstein J: The Secret Life of Alfred Kinsey. *Commentary* 1998 (Jan); 35-9.

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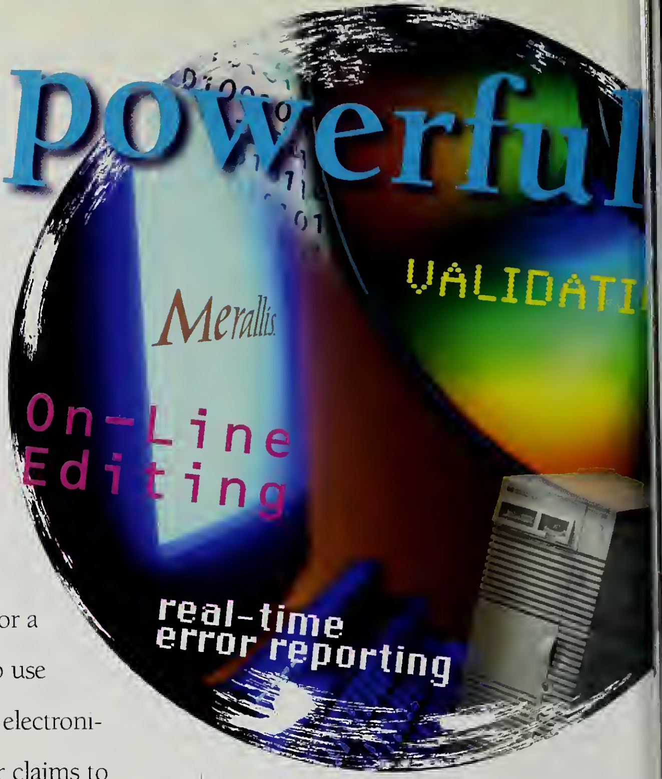

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This Month's Reading in Review

TIMOTHY B. NORBECK

"Patients have got to know beyond a shadow of doubt that physicians are leading the way with their best interests in mind, so they'll be right behind us. We clearly need to move in the direction of universal access, put aside our differences and create a shared vision. We cannot consider our legislators to be nameless, faceless bureaucrats. Get to know them, and help move the vision well beyond the house of medicine."

AMA President-elect Nancy Dickey, M.D.
California Physician (December 1997)

"Welcome to the next health-care debate.... This time it's not about Washington changing the system but about keeping the free market from changing it too quickly.... And it's being waged not on behalf of the 41 million without insurance but of the 70 million who have enrolled in health-maintenance organizations."

Time (8 December 1997)

"A main goal is to restore the doctor-patient relationship—which is broken in many places by insurance company accountants who second-guess the judgments of physicians or put business profits ahead of patients' health."

Senator Edward Kennedy (D-Mass.), speaking at the Capitol Hill forum on the need for managed-care reform.
Hartford Courant (17 December 1997)

"It has some good things and some not so good things. I think they missed perhaps the most important thing they could have done. And that is, roughly a *third* of the people in this country do *not* have a *choice* of health-care plans. I was really hoping that the national task force would recommend ... that the Congress re-pass something like that HMO act that said people could have choices of plans."

Stanford University health economist Alain Enthoven, commenting on President Clinton's endorsement of his task force's set of patients' rights.
News Hour, PBS (20 November 1997)

According to the *Chronicle of Philanthropy*, New Englanders do not do well in contributing to charities.... Massachusetts ranked 44th of the 50 states in charitable giving.... Vermont, Maine, New Hampshire, and Rhode Island ranked 47th through 50th.... Connecticut out-contributed its New England neighbors, finishing in 36th place.

Hartford Courant (2 December 1997)

Most Americans get their health and medical information from the media, according to a new survey conducted for the National Health Council.... Television surpassed physicians, 40% to 36%, as the primary source of health and medical news, while 35% of respondents said they look to magazines for their health news.... Those with chronic health conditions, however, turn to their doctors first and magazines second for health news.... Only 4% of all Americans get their health news from the radio, and only 2% get such news from the Internet.

The most trusted sources of health news are, in order, doctors 93%; nurses 92%; pharmacists 92%, print and broadcast media 81% to 87%, the Surgeon General 86%, and the FDA 83%.... However most Americans (68%) believe that the media "often contradict themselves."

National Health Council release
(11 December 1997)

"The British government has announced a plan that called for a far-reaching effort to overhaul the National Health Service, the country's 49-year-old system of socialized medicine."... The health service will save some $1.6 billion by abolishing red tape, cutting bureaucracy, and giving more power to the country's 35,000 general practitioners. "At the end of September, 1.2 million patients were waiting for treatment, more than 17,000 more than had been waiting in July. And the lines are expected to lengthen during the winter months."

New York Times (19 December 1997)

Thanks for the memory: An Austrian fined for mooning German Chancellor Helmut Kohl has asked that Kohl appear in court to identify the defendant's behind.

The Washington Monthly (Decembe, 1997)

Only in America: A man was arrested for burglary in Wood River, Ill., after police found him in a hospital.... The burglar had attempted to move a safe, but it fell on his hand, and his glove was found underneath it, still containing the top part of the middle finger of the burglar's left hand (which was exactly the part the man was missing when he reported to the hospital).... Said one officer, "He admitted it. What can you do if your finger's there?"

America Online (8 December 1997)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Round Table Discussion

Letter to the Editor: It has come to my attention at a recent round table discussion that some pediatricians are following recommendations of our ENT colleagues (as stated by them) to treat some daycare children prophylactically with low dose antibiotics for colds to prevent recurrent otitis.

The medication used is gantrisin or amoxicillin. It is being prescribed in half the recommended dose for four to five days to those children who have a history of recurrent otitis with colds.

I did not realize that this type of therapy was being used in this climate of concern regarding bacterial resistance and the terrible problems associated with this. There is no better way to promote increased resistance than that described in the body of this letter.

I would appreciate any comment by any of my colleagues concerning this problem.

Arnold A. Heiger, M.D.
Cheshire

In Response to *Thiamine Deficiency* Article

Letter to the Editor: I was delighted to read the recent article *Lactic Acidosis Traced to Thiamine Deficiency Related to Nationwide Shortage of Multivitamins for Total Parenteral Nutrition—United States, 1997* (*Conn Med* 1997; 10:663). As treating physicians, we certainly need to be reminded that thiamine deficiency can be a crucial factor in morbidity and mortality, not only in situations of lactic acidosis and neurological deficit, but also in refractory congestive heart failure as well.

A review of the clinical research has shown that thiamine deficiency may occur in patients receiving diuretics for longer than three months.[1,2] Diuretics, especially loop diuretics, can lead to excessive thiamine excretion resulting in thiamine loss creating a state of thiamine depletion that may further contribute to worsening congestive heart failure. When thiamine deficient patients with congestive heart failure are given IV thiamine some will demonstrate a dramatic increase in left ventricular ejection fraction as measured by echocardiography.

As a cardiovascular specialist, I have observed similar results in my own practice and wish to alert other patients about the crucial role that thiamine deficiency may play in problematic and refractory congestive heart failure. Thiamine deficiency, for any patient with recurrent congestive heart failure and unsatisfactory quality of life, despite conventional and alternative therapies, must be thought of as a contributing factor.

If not recognized and treated, many patients taking long-term diuretics may require additional thiamine and B vitamin support. It is also important to counsel this population on long-term diuretics to be cautious about their caffeine and alcoholic intake because these "drugs" may further contribute to the washout effect of the precious B vitamins.

Since B vitamins, including thiamine, are water soluble and virtually have no downside, I would strongly recommend them to anyone on long-term diuretic therapy, particularly those on powerful loop diuretics such as Lasix or Bumex. Simple thiamine supplementation is sometimes just the thing a physician can add to his therapeutic recommendations which may enhance the quality of life for a patient with congestive heart failure.

Stephen T. Sinatra, M.D.
Manchester

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1. Leslie D, Gheorghiade M: Is there a role for thiamine supplementation in the management of heart failure? *Am Heart J* 1996; 131:1248–50.
2. Chen MR, Chen LT, Gold M, Boyce HW: Plasma and erythocryte thiamine concentrations in geriatric outpatients. *J Am Coll Nutr* 1996; 15:231–6.

In Response to Dr. Lenaz's Letter "Ethics in Managed Care"

Letter to the Editor: I strongly suspect that I wasn't the only one who was surprised and dismayed by some of the comments made by Maria Lenaz, M.D., Medical Director, Oxford Health Plans, Connecticut, in her letter entitled "Ethics in Managed Care" which appeared in the November 1997 issue of *Connecticut Medicine.*

While Dr. Lenaz made a noble attempt to draw a similarity between the medical ethics which physicians utilize in dealing with their patients and the business ethics which HMOs utilize in interacting with their subscribers, she correctly acknowledged that physician obligations to their patients are, at times, competing and in conflict with doctors' obligations to HMOs. It is precisely this point—the conflicting obligations between patient and HMO—which disturbs most physicians. Physicians' first loyalty must always be to their patients: not, "as a group," but as individuals!

Dr. Lenaz states, "under the ethical principle of justice-equity, health plans and their physicians should allocate resources in a way that fairly distributes benefits and financial burdens among the members." HMOs may subscribe to an ethic of "justice-equity," but I couldn't find it anywhere in the Hippocratic Oath or the AMA's Code of Ethics. Such a "principle" is evident in the discredited Tuskegee study, and in the Swedish government's recently revealed policy of sterilizing "undesirables." And, of course, this "principle" reached it's pinnacle of development with the Nazi "medical ethic" of "lebensunwertes Leben"—a life unworthy of life itself! But I wonder how many of our physicians, or more importantly patients, are aware that, because they are enrolled in an HMO, they "have a duty to promote the good of the members as a group."

If the guiding principle of "justice-equity" was commonly known by patients and physicians, I suspect there would be far fewer of both counted within the ranks of HMOs! Most people rightfully want their physician to do everything medically feasible to help them if they become seriously ill. People don't want their doctors worrying about staying "within the limits of the resources available for the entire HMO population." Most people believe that what they are getting with an HMO is a health insurance plan, not a social redistribution health-care scheme!

HMOs shouldn't claim to have an ethical responsibility to their clients as a group ("justice-equity"), and then not let that patient population have a voice in the who, what, when, and where of the distribution of resources through their own "health plan." And please notice—I did not use the term "health insurance plan," because insurance plans assume risk for a particular population. HMOs are finding clever ways, through various financial reimbursement methods, to pass along the risk to physicians and other providers. HMOs are becoming merely expensive third-party administrators. And, if an entity is going to ration access and redistribute health-care resources, it certainly should not be a bottom-line oriented HMO!

Finally, how does an HMO resolve the conflict between its ethical responsibility of letting patients make their own health-care decisions ("autonomy"), with its other "ethical duty"—"to promote the good of the members as a group"? It can't! Obviously, there is an unresolvable dichotomy between the two, which clearly exposes the folly of Dr. Lenaz's "ethics" in managed care.

Stephen R. Katz, M.D.
Fairfield

In Response to Dr. Chotkowski's Letter

Letter to the Editor: I read with a mixture of mirth and sadness the letter by Mr. Chotkowski in the June issue of *Connecticut Medicine* regarding his review of chiropractic in general, and New York Chiropractic College specifically. My mirth was elicited by Mr. Chotkowski's unbridled bias against, and appalling ignorance of, the science, art, and philosophy of chiropractic. While it is not uncommon to witness this kind of hard-line, dodmatic attitude—regardless of the reams of research published in the last 20 years—there are few who will unabashedly parade their prejudice like Mr. Chotkowski.

My sadness came from the fact that *Connecticut Medicine*—an otherwise worthy publication—would print a letter like his. Mr. Chotkowski's glaring lack of objectivity flies in the face of responsible journalism.

For instance: Mr. Chotkowski suggests that New York Chiropractic College had no research department. Obviously he did not care to ask. He also did not care to find out that indeed the library was well equipped with scientific journals. He suggests that the chiropractic curriculum is a three-year program when it is a 10-semester program with over 4,900 credit hours of didactic and practical education—on par with medical college programs. While he took the time to go to the college, he did not apparently take the time to learn anything. I believe his *modus operandi* was, "don't confuse me with the truth."

The biggest problem that Mr. Chotkowski seemed to have was understanding that chiropractic works from a different paradigm than medicine. To compare chiropractic with medicine is like apples and oranges. He was right, we do not "diagnose and treat specific diseases." That is the practice of medicine. Is his world so small that nothing can exist outside of this realm?

Chiropractic focuses on the connection between structure and function. Specifically between the spine and the function of the nervous system. The aim of chiropractic is not to treat disease, but to detect and correct vertebral subluxation; to remove that which interferes with the innate healing capacity of the human body. As it happens, numerous studies show the beneficial effects of this type of care on people who suffer from many different disease conditions. Suggesting that there is no evidence to support the "theory" of chiropractic leads one to believe that it is Mr. Chotkowski's library that is devoid of scientific journals.

Mr. Chotkowski would like to see the elimination of the chiropractic profession. Need we remind him of the United States Supreme Court ruling against the American Medical Association for trying to do just that?

Since that landmark decision to uphold a lower court's guilty verdict against the AMA, there has been an ever-increasing, constructive dialogue between medical doctors and chiropractors. I personally work with several physicians who refer patients to this office for chiropractic care. Patients who suffer from conditions ranging from low back pain to otitis media. They refer *because they have found that their patients benefit from the referral.* This bridge between our professions only serves to help our patients. Mr. Chotkowski's false and inflammatory letter—and your printing of it—is damaging to this bridge and does not serve any productive purpose.

I hope to see more constructive and objective articles in future issues.

Dr. Timothy C. Merrick, D.C.
Board of Directors
Connecticut Chiropractic Council

Dr. Chotkowski Responds to Dr. Merrick

Chiropractic Timothy Merrick's letter apparently expresses the views of the Connecticut Chiropractic Council and again reveals the true nature of the chiropractic dilemma. The letter states that chiropractic admittedly quote, "cannot diagnose and treat specific diseases," and that the "aim is not to treat disease, but to detect and correct vertebral subluxation."

The problem with that aim is that the existence of a subluxation has never been demonstrated and all scientific evidence of its existence is to the contrary. In fact, the recent attempt of the 16 chiropractic college presidents even to define a subluxation falls short of any clear description, to wit:[1]

"Subluxation is a complex of functional and/or structural and/or pathologic changes that compromise neural integrity and may influence organ systems' function and health. A subluxation is evaluated, diagnosed and managed through use of chiropractic procedures based on the best available rational empirical evidence"—terms that have been described as chiroprattle.

As for the Wilk *vs* the AMA, Federal Judge Susan Getzendanner did not find chiropractic to be a valid health-care system, but only that it was illegal for the AMA to engage in an antitrust boycott of a licensed practice.

Regarding the creation of a constructive dialogue and bridging the gap between unscientific chiropractic and scientific medicine, the quickest way this can be accomplished is for chiropractic to abandon its ludicrous theory and convert its colleges into accredited medical schools, —as the osteopaths have done.

L.A. Chotkowski, M.D.
Kensington

REFERENCE

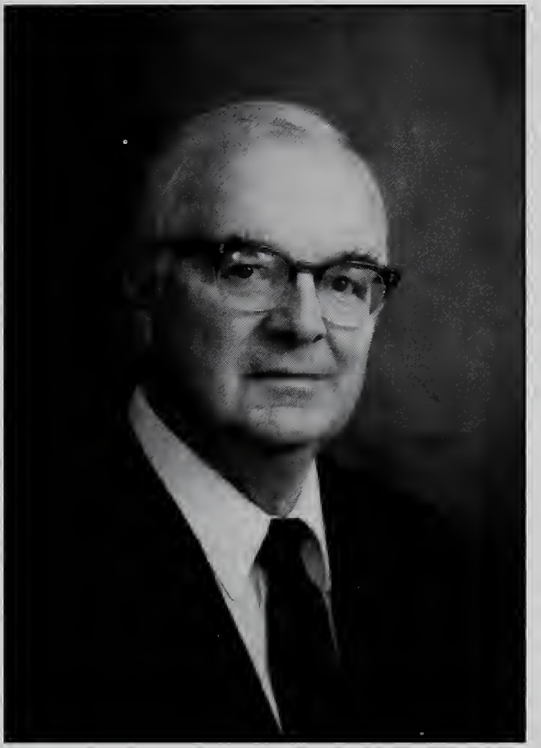
1. Rosner AL: Director of Research, Foundation for Chiropractic Education and Research, Monogram, *"The Role of Subluxation in Chiropractic."*

Surety Bond Requirment

It has come to our attention that bond companies in New York State may be trying to capitalize on a possible Medicare ruling to urge physicians who distribute any durable medical equipment to purchase surety bonds. We are concerned that this activity may be going on in other states as well. **The purchase of such bonds is premature.**

As a result of the Balanced Budget Act, the Health Care Financing Administration (HCFA) is developing a proposed regulation to address what entities are required to purchase surety bonds in order to distribute durable medical equipment. It is our understanding that HCFA is considering requiring anyone using a supplier ID to bill Medicare to post a surety bond. After HCFA issues the proposed regulation there will be a comment period. **HCFA, however, will not require the purchase of surety bonds by physicians officers for durable medical equipment until the regulationals final.** Once the regulation is final, each supplier will receive notification from the National Supplier Clearinghouse regarding requirements for the bonds. Please note that if a bond is required not all bond companies will be acceptable to HCFA. HCFA will only accept bonds purchased from companies listed on the latest revision of the Department of Treasury Circular 570 Companies Holding Certificates of Aurthority a acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies.

Richard A. Deem
Vice President, Federal Affairs and Coalitions
AMA Fax 1/12/98



ROBERT R. McDONNELL, M.D.

Robert Ralph McDonnell, M.D., Treasurer of the Connecticut State Medical Society, died 11 December 1997, at age 78. He was born 16 August 1919 in New Haven, the son of the late Dr. Ralph A. McDonnell, a former president of CSMS, and Genevieve Bettcher. A memorial service was held on 15 December in the Battell Chapel at Yale.

Dr. McDonnell graduated from Colby College in Waterville, Maine in 1942, and received his medical degree from Jefferson Medical College in Philadelphia in 1945. He was a captain in the Army from 1946 to 1948. He completed residencies in neurosurgery at New Haven Hospital, Yale School of Medicine, and at Hartford Hospital from 1948 to 1952. He was an attending physician at Yale-New Haven Hospital and The Hospital of Saint Raphael from 1952 until his retirement in December 1996.

Dr. McDonnell was a member of the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, the New England Neurological Society, the American Board of Neurological Surgeons-Diplomate, and the American Medical Association. He was the treasurer of the Connecticut State Medical Society, serving with distinction since 1985. He was also a past president of the New Haven County Medical Association and of the New Haven Medical Association. He was a member of the New Haven Country Club, the Quinnipiac Club, the Yale Club of New Haven, Mory's, the New Haven Gridiron Club, and the Yale Hockey Association.

Besides his wife, Ruth Morris McDonnell, he leaves six daughters, Donna Kellaher, Bonnie DuBrino, Carole Doherty, Deborah Colwell, Patricia Clifton, and Joan O'Connor, a brother, William E. McDonnel of Branford, and 17 grandchildren. Memorial contributions may be made to The Hospital of Saint Raphael Foundation, 1450 Chapel Street, New Haven, CT 06511.

Robert J. Brunell
Director of Scientific Affairs, CSMS

The C. Anderson Aldrich Award in Child Development

For Outstanding Contributions to the
Field of Child Development

was giving to

Morris A. Wessel, M.D.

at the

Section of Developmental and Behavioral Pediatrics American Academy of Pediatrics Annual Meeting

Sunday, 2 November 1997 in New Orleans, LA

The C. Anderson Aldrich Award is made possible by a
continuing grant from Ross Products Division

Morris Wessel, M.D. was born in Providence, Rhode Island, and grew up in New London, Connecticut. Dr. Wessel resides with his wife Irmgard Wessel in New Haven, Connecticut. They have three sons and a daughter.

He received his B.A. degree in 1939 from Johns Hopkins University and his M.D. degree in 1943 from Yale University School of Medicine. He interned at Babies Hospital in New York. After a tour in military service, he received an appointment as Pediatric Fellow at the Mayo Clinic in Rochester, Minnesota. In 1948 he received an appointment as a Rooming-in Fellow at Yale-New Haven Hospital where he worked in close association with Dr. Edith B. Jackson.

Dr. Wessel was appointed Instructor in Pediatrics at the Yale Medical School in 1950, and in 1975, was appointed Clinical Professor of Pediatrics. He was appointed Assistant Director of the Pediatric Clinic at the Yale-New Haven Hospital, and was director of that clinic from 1952 to 1957. In 1967 he was appointed as the Consulting Pediatrician at the Clifford Beers Child Guidance Clinic in New Haven. He was elected president of the New England Pediatric Society in 1970, and served as a member of the Executive Board of the Child Welfare League of America.

Over a period of 42 years (1951–1993), Dr. Wessel practiced primary pediatrics in New Haven, and during that time he was much liked and respected. He served as an exemplary role model to thousands of medical students and hundreds of pediatric residents because of his active mind, his wide range of interests, and his great concern for the welfare of his patients and families. He has been an astute observer and an articulate reporter of a number of phenomena seen in practice. Through his productive and creative office research, Dr. Wessel has influenced thousands of pediatricians, family practitioners, and child psychiatrists.

Because of his innovative and tireless efforts on behalf of children and families, Dr. Wessel has been the recipient of many awards. In 1986, he was awarded the Connecticut State Health Department Award for Outstanding Contribution to the Health of Mothers and Children. In 1993, he received the Practitioner Research Award of the American Academy of Pediatrics.

Dr. Wessel's interest in pediatric behavior and development arose during his association with Dr. C.A. Aldrich and Dr. Benjamin Spock. He was written and presented over 200 publications and presentations, and is the author of the book, *Parent's Book for Raising a Healthy Child,* published in 1987.

Dr. Wessel has been a master of the office-based observational study period. In his pursuit of new knowledge about common issues in pediatrics, he has served as an outstanding model of a practitioner/researcher. His unique quality has been to examine complex phenomena encountered in practice but not adequately covered in current text books or journal articles. For instance, he would investigate a problem thoroughly, develop a working hypothesis, implement the plan in practice, and then present his ideas to his fellow physicians or as papers for parents. Someone noted in reference to him, "Clinical observations of pediatric practice and issues, carefully and wisely interpreted, and then convincedly transmitted, represent scholarship in its highest form."

His topics of interest have included colic, adoption (a review in the *New England Journal of Medicine),* lead poisoning, bereavement, prenatal visits, postpartum rooming-in, corporal punishment, teenage pregnancy, the satisfactions of practice, feeding techniques, and thyroid dysfunction in pregnancy. His article on colic in *Pediatrics* in 1954 is still often quoted. His 1963 article on prenatal pediatric visits stimulated other colleagues to do the same. More recently he has provided much insight and understanding about the impact of death and dying in children and their families.

Dr. Wessel is a pediatrician who is highly deserving, and his work has had a significant impact on those who care for children. He is truly a renaissance pediatrician and broad based scholar. It is a great honor and pleasure for the Section of Developmental and Behavioral Pediatrics to recognize and thank Dr. Morris Wessel with the C. Anderson Aldrich Award.

William Coleman, M.D.

IN MEMORIAM

BERGENDAHL, GILBERT T., Tufts University School of Medicine, 1961. Dr. Bergendahl, a surgeon, was former chief of surgery at The William W. Backus Hospital and a former health director for the town of Franklin. He was a member of the New London County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Bergendahl died 20 November 1997 at the age of 62.

BOGIN, MAXWELL, Yale University School of Medicine, 1926. Dr. Bogin was chief of pediatrics at Bridgeport Hospital from 1948 to 1967. He was former state chairman of the Connecticut Chapter of the Academy of Pediatrics. He served as chairman of the medical advisory board of the Rehabilitation Center of Fairfield County and as consultant in pediatrics to the Connecticut State Department of Health. Dr. Bogin was a founding partner of the Children's Medical Group in Bridgeport and supervised pediatric clinics in Easton and Monroe. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Bogin died 2 December 1997 at the age of 95.

CHESTER, LEWIS, University of Vermont College of Medicine, 1938. Dr. Chester, former chief of the medical staff at Mount Sinai Hospital in Hartford, practiced otolaryngology and plastic surgery in Hartford for 40 years. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society where he served on the Sports Medicine Committee in the early 1980s, and the American Medical Association. Dr. Chester died 23 October 1997 at the age of 85.

CONWAY, DAVID F., Columbia University College of Physicians and Surgeons, 1937. Dr. Conway was an obstetrician and gynecologist at The Hospital of St. Raphael in New Haven for 38 years and served as chief of staff and chairman of the department of obstetrics and gynecology. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Conway died 4 December 1997 at the age of 89.

CRONIN, ROBERT J., New York Medical College, 1959. Dr. Cronin was an anesthesiologist and senior partner with the Hartford Anesthesiology Group. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Cronin died 18 October 1997 at the age of 64.

EDSON, REGINALD C., Jefferson Medical College of Thomas Jefferson University, 1931. In his early years of practice, Dr. Edson was assistant superintendent and medical director at Hopemont Tuberculosis Hospital in West Virginia. In 1942, he accepted a Connecticut appointment as assistant director of the state Tuberculosis Commission. From 1952 to 1961 he served as superintendent of Cedarcrest Hospital in Newington and was then named deputy commissioner of health. Dr. Edson was a member of the Hartford County Medical Association serving as their president from 1967 to 1968 and as a delegate to the Connecticut State Medical Society for 11 years, the Connecticut State Medical Society where he was active on numerous committees during the 1960s, and the American Medical Association. Dr. Edson died 7 December 1997 at the age of 92.

FENAUGHTY, RICHARD W., State University of New York College of Medicine, 1957. Dr. Fenaughty joined the Grove Hill Medical Center as an obstetrician-gynecologist in 1963. He served as assistant chief of OB/GYN at New Britain General Hospital from 1976–1986, as chief of staff from 1986–1991, and as vice president of medical affairs and the chief medical administrator from 1991-1993. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Fenaughty died 4 December 1997 at the age of 68.

GALLIVAN, JOHN N., Tufts University School of Medicine, 1935. In addition to his medical degree, Dr. Gallivan received a certificate of occupational medicine and industrial hygiene from Yale University in 1947. He served as the Town of East Hartford Health Director for 39 years. Dr. Gallivan practiced medicine for 50 years beginning with a private practice in East Hartford and later serving as chief medical officer at Pratt & Whitney/United Technologies. Active in area medical groups, Dr. Gallivan was past president and founder of the East Hartford Medical Society and the first president of the East Hartford-Glastonbury Medical Society. He was a member and past president of the Hartford County Medical Association and served as a delegate to the Connecticut State Medical Society during the 1960s, the Connecticut State Medical Society where he was served on many committees relating to public health and held the position of president from 1960 to 1961, and the American Medical Association. Dr. Gallivan died 24 October 1997 at the age of 85.

KOGUT, HENRY V., New York Medical College, 1943. Dr. Kogut practiced ophthalmology in Bridgeport and Stratford for 49 years. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Kogut died 18 October 1997 at the age of 79.

LANGNER, HELEN P., Yale University School of Medicine, 1922. Dr. Langner, a psychiatrist, was one of the first women ever admitted to Yale University School of Medicine. She worked as a psychiatrist in several areas of the country. In 1929 she taught women's health at Vassar College. After 10 years she set up a private practice in New York City. At the age of 91 she became a consultant at Milford Hospital and was considered the oldest active physician at a hospital in the nation. Dr. Langner was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Langner died 10 December 1997 at the age of 105.

LITTLE, MERVYN H., Harvard Medical School, 1935. Dr. Little initially practiced medicine in Fairfield, relocating to Willimantic in 1946. He maintained a joint office with his wife for his family practice and her psychiatric practice until his retirement. Dr. Little was active on the staff of Windham

Community Memorial Hospital. He was a cofounder of the Natchaug Hospital in 1954 and served as medical director and president for years. He was a member of the Windham County Medical Association, the Connecticut State Medical Society where he was active on committee's during the 1960s and 1970s, and the American Medical Association. Dr. Little died 1 December 1997 at the age of 89.

LITTLE, OLGA A., Boston University School of Medicine, 1935. Dr. Little practiced psychiatry in Willimantic and was associated with Windham Community Memorial Hospital. She was a cofounder and medical director of Natchaug Hospital until her retirement in 1982. Dr. Little was a member of the Windham County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Little died 30 November 1997 at the age of 87.

MARSH, RAYMOND R., Harvard Medical School, 1945. Dr. Marsh practiced medicine in West Hartford and served on the staff of Hartford Hospital for over 35 years, retiring in 1991. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Marsh died 22 October 1997 at the age of 76.

McDONNELL, ROBERT R., Jefferson Medical College of Thomas Jefferson University, 1945. Dr. McDonnell maintained a private practice in neurological surgery in New Haven and was an attending physician at Yale New Haven Hospital and The Hospital of St. Raphael from 1952 until his retirement in 1996. He was a clinical instructor in neurological surgery at Yale School of Medicine since 1952. He was active in many local, state, and national organizations including past president of the New Haven Medical Association. Dr. McDonnell was a member and past president of the New Haven County Medical Association and served as a delegate to the Connecticut State Medical Society during the 1970s, the Connecticut State Medical Society where he served as treasurer since 1985 and was active on numerous committee's for nearly 20 years, and the American Medical Association. Dr. McDonnell died 11 December 1997 at the age of 78.

PHELPS, MAXWELL O., McGill University Faculty of Medicine, Montreal, 1929. At Hartford Hospital, Dr. Phelps served as the director of the department of medicine, president of the staff, chairman of the Graduate Medicine Committee, director of the School of Nursing, editor at the Hartford Hospital Bulletin, and as a corporator. Dr. Phelps was also associated with Cedarcrest Hospital, The Institute of Living, and was a director of Gaylord Hospital and a trustee of Kingswood-Oxford School. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society where he served on the Committee on Hospitals during the 1960s, and the American Medical Association. Dr. Phelps died 9 December 1977 at the age of 95.

PROKOP, JAMES D., Yale University School of Medicine, 1959. Dr. Prokop was director of the department of neurosurgery at Stamford Hospital and St. Joseph Medical Center from 1976 to 1981 and director of neurosurgery at Stamford Hospital from 1994 to 1995. He maintained a private practice in Stamford and was associated with Stamford Hospital, St. Joseph Medical Center, and Greenwich Hospital. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Prokop died 1 December 1997 at the age of 64.

REYNOLDS, WHITMAN, Columbia University College of Physicians and Surgeons, 1931. Dr. Reynolds served as medical director of the Medical Equitable Life Assurance Society and as president of the American Life Insurance Medical Directors Association. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society where he served on the Medical Economic and Insurance Committee from 1967 until 1972, and the American Medical Association. Dr. Reynolds died 29 October 1997 at the age of 92.

SCHULTZ, MARTIN, New York University School of Medicine, 1943. Dr. Schultz practiced internal medicine in Westport from 1951 until he retired in 1991. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Schultz died 24 October 1997 at the age of 77.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

Opportunities* should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians making inquiries of such *opportunities.

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Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

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Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

Consumer Concern Or Complaint Form Regarding Group Or Individual Health Insurance Including Managed Care Plans

To Be Submitted To
THE CONNECTICUT DEPARTMENT OF INSURANCE
CONSUMER AFFAIRS DIVISION
P.O. BOX 816
HARTFORD, CT 06142-0816

Phone: (860) 297-3900 or 1-800-203-3447 Fax: (860) 297-3872

The Consumer Affairs Division of the Department of Insurance receives, reviews and responds to complaints and inquiries from state residents concerning insurance related problems. The staff examines each complaint to determine whether statutory requirements and contractual obligations within the commissioner's jurisdiction have been fulfilled. The Consumer Affairs Division coordinates the resources available within the Department to address consumer complaints.

In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

Name of person filing the concern or complaint:

____

Address: ______________________________________

Phone where the Department can contact you: (_____) ______________________

This concern or complaint concerns the following Insurance Company or Managed Care Plan: ______________________

Policy Number: ______________________

Name of Policyholder: ______________________

Name of Enrollee: ______________________

Name of Patient: ______________________

Patient is ___ **self** ___ **dependent** ___**other** (explain)______________________

The following is a detailed description of the concern or complaint:

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BRIEF SUMMARY

ZYBAN™ (bupropion hydrochloride)

Sustained-Release Tablets

The following is a brief summary only; see full prescribing information for complete product information.

CONTRAINDICATIONS: ZYBAN is contraindicated in patients with a seizure disorder.

ZYBAN is contraindicated in patients treated with WELLBUTRIN® (bupropion hydrochloride) Tablets, WELLBUTRIN SR® (bupropion hydrochloride) Sustained-Release Tablets, or any other medications that contain bupropion because the incidence of seizure is dose dependent.

ZYBAN is contraindicated in patients with a current or prior diagnosis of bulimia or anorexia nervosa because of a higher incidence of seizures noted in patients treated for bulimia with the immediate-release formulation of bupropion.

The concurrent administration of ZYBAN and a monoamine oxidase (MAO) inhibitor is contraindicated. At least 14 days should elapse between discontinuation of an MAO inhibitor and initiation of treatment with ZYBAN.

ZYBAN is contraindicated in patients who have shown an allergic response to bupropion or the other ingredients that make up ZYBAN.

WARNINGS: Patients should be made aware that ZYBAN contains the same active ingredient found in WELLBUTRIN and WELLBUTRIN SR used to treat depression, and that ZYBAN should not be used in combination with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion.

Because the use of bupropion is associated with a dose-dependent risk of seizures, *clinicians should not prescribe doses over 300 mg/day for smoking cessation.* The risk of seizures is also related to patient factors, clinical situation, and concurrent medications, which must be considered in selection of patients for therapy with ZYBAN.

- **Dose: *For smoking cessation, doses above 300 mg/day should not be used.* The seizure rate associated with doses of sustained-release bupropion up to 300 mg/day is approximately 0.1% (1/1,000). This incidence was prospectively determined during an 8-week treatment exposure in approximately 3,100 depressed patients. Data for the immediate-release formulation of bupropion revealed a seizure incidence of approximately 0.4% (4/1,000) in depressed patients treated at doses in a range of 300 to 450 mg/day. In addition, the estimated seizure incidence increases almost tenfold between 450 and 600 mg/day.**
- **Patient factors: Predisposing factors that may increase the risk of seizure with bupropion use include history of head trauma or prior seizure, central nervous system (CNS) tumor, and concomitant medications that lower seizure threshold.**
- **Clinical situations: Circumstances associated with an increased seizure risk include, among others, excessive use of alcohol; abrupt withdrawal from alcohol or other sedatives; addiction to opiates, cocaine, or stimulants; use of over-the-counter stimulants and anorectics; and diabetes treated with oral hypoglycemics or insulin.**
- **Concomitant medications: Many medications (e.g., antipsychotics, antidepressants, theophylline, systemic steroids) and treatment regimens (e.g., abrupt discontinuation of benzodiazepines) are known to lower seizure threshold.**

Recommendations for Reducing the Risk of Seizure: Retrospective analysis of clinical experience gained during the development of bupropion suggests that the risk of seizure may be minimized if

- **the total daily dose of ZYBAN does *not* exceed 300 mg (the maximum recommended dose for smoking cessation), and**
- **the recommended daily dose for most patients (300 mg/day) is administered in divided doses (150 mg twice daily).**
- **No single dose should exceed 150 mg to avoid high peak concentrations of bupropion and/or its metabolites.**
- **ZYBAN should be administered with extreme caution to patients with a history of seizure, cranial trauma, or other predisposition(s) toward seizure, or patients treated with other agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of a benzodiazepine) that lower seizure threshold.**

Potential for Hepatotoxicity: In rats receiving large doses of bupropion chronically, there was an increase in incidence of hepatic hyperplastic nodules and hepatocellular hypertrophy. In dogs receiving large doses of bupropion chronically, various histologic changes were seen in the liver, and laboratory tests suggesting mild hepatocellular injury were noted.

PRECAUTIONS:

General: ***Allergic Reactions:*** Anaphylactoid reactions characterized by symptoms such as pruritus, urticaria, angioedema, and dyspnea requiring medical treatment have been reported at a rate of about 1-3 per thousand in clinical trials of ZYBAN. In addition, there have been rare spontaneous postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion.

Insomnia: In the dose-response smoking cessation trial, 29% of patients treated with 150 mg/day of ZYBAN and 35% of patients treated with 300 mg/day of ZYBAN experienced insomnia, compared to 21% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.6% of patients treated with ZYBAN and none of the patients treated with placebo.

In the comparative trial, 40% of the patients treated with 300 mg/day of ZYBAN, 28% of the patients treated with 21 mg/day of HABITROL® (nicotine transdermal system) (NTS), and 45% of the patients treated with the combination of ZYBAN and NTS experienced insomnia compared to 18% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.8% of patients treated with ZYBAN and none of the patients in the other three treatment groups.

Insomnia may be minimized by avoiding bedtime doses and, if necessary, reduction in dose.

Psychosis, Confusion, and Other Neuropsychiatric Phenomena: In clinical trials with ZYBAN conducted in nondepressed smokers, the incidence of neuropsychiatric side effects was generally comparable to placebo. Depressed patients treated with bupropion in depression trials have been reported to show a variety of neuropsychiatric signs and symptoms including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment.

Activation of Psychosis and/or Mania: Antidepressants can precipitate manic episodes in bipolar disorder patients during the depressed phase of their illness and may activate latent psychosis in other susceptible individuals. The sustained-release formulation of bupropion is expected to pose similar risks. There were no reports of activation of psychosis or mania in clinical trials with ZYBAN™ conducted in nondepressed smokers.

Use in Patients With Systemic Illness: There is no clinical experience establishing the safety of ZYBAN in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, care should be exercised if it is used in these groups. Bupropion was well tolerated in depressed patients who had previously developed orthostatic hypotension while receiving tricyclic antidepressants, and was generally well tolerated in a group of 36 depressed inpatients with stable congestive heart failure (CHF). However, bupropion was associated with a rise in supine blood pressure in the study of patients with CHF, resulting in discontinuation of treatment in two patients for exacerbation of baseline hypertension.

In the comparative trial, 6.1% of patients treated with the combination of ZYBAN and NTS had treatment-emergent hypertension compared to 2.5%, 1.6%, and 3.1% of patients treated with ZYBAN, NTS, and placebo, respectively. The majority of these patients had evidence of preexisting hypertension. Three patients (1.2%) treated with the combination of ZYBAN and NTS and one patient (0.4%) treated with NTS had study medication discontinued due to hypertension compared to none of the patients treated with ZYBAN or placebo. Monitoring for treatment-emergent hypertension is recommended in patients receiving the combination of ZYBAN and NTS.

Because bupropion hydrochloride and its metabolites are almost completely excreted through the kidney and metabolites are likely to undergo conjugation in the liver prior to urinary excretion, treatment of patients with renal or hepatic impairment should be initiated at reduced dosage as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible toxic effects of elevated blood and tissue levels of drug and metabolites.

Information for Patients: See PATIENT INFORMATION at the end of the full prescribing information for the text of the separate leaflet provided for patients. Physicians are advised to review the leaflet with their patients and to emphasize that ZYBAN contains the same active ingredient found in WELLBUTRIN and WELLBUTRIN SR used to treat depression and that ZYBAN should not be used in conjunction with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion hydrochloride.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions: In vitro studies indicate that bupropion is primarily metabolized to hydroxybupropion by the CYP2B6 isoenzyme. Therefore, the potential exists for a drug interaction between ZYBAN and drugs that affect the CYP2B6 isoenzyme metabolism (e.g., orphenadrine and cyclophosphamide). The threohydrobupropion metabolite of bupropion does not appear to be produced by the cytochrome P450 isoenzymes. No systemic data have been collected on the metabolism of ZYBAN following concomitant administration with other drugs or, alternatively, the effect of concomitant administration of ZYBAN on the metabolism of other drugs.

Animal data indicated that bupropion may be an inducer of drug-metabolizing enzymes in humans. However, following chronic administration of bupropion, 100 mg t.i.d. to 8 healthy male volunteers for 14 days, there was no evidence of induction of its own metabolism. Because bupropion is extensively metabolized, the coadministration of other drugs may affect its clinical activity. In particular, certain drugs may induce the metabolism of bupropion (e.g., carbamazepine, phenobarbital, phenytoin), while other drugs may inhibit the metabolism of bupropion (e.g., cimetidine).

Studies in animals demonstrate that the acute toxicity of bupropion is enhanced by the MAO inhibitor phenelzine (see CONTRAINDICATIONS).

Limited clinical data suggest a higher incidence of adverse experiences in patients receiving concurrent administration of bupropion and levodopa. Administration of ZYBAN to patients receiving levodopa concurrently should be undertaken with caution, using small initial doses and gradual dose increases.

Concurrent administration of ZYBAN and agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of benzodiazepines) that lower seizure threshold should be undertaken only with extreme caution (see WARNINGS).

Physiological changes resulting from smoking cessation itself, with or without treatment with ZYBAN, may alter the pharmacokinetics of some concomitant medications, which may require dosage adjustment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Lifetime carcinogenicity studies were performed in rats and mice at doses up to 300 and 150 mg/kg per day, respectively. These doses are approximately ten and two times the maximum recommended human dose (MRHD), respectively, on a mg/m^2 basis. In the rat study, there was an increase in nodular proliferative lesions of the liver at doses of 100 to 300 mg/kg per day (approximately three to ten times the MRHD on a mg/m^2 basis); lower doses were not tested. The question of whether or not such lesions may be precursors of neoplasms of the liver is currently unresolved. Similar liver lesions were not seen in the mouse study, and no increase in malignant tumors of the liver and other organs was seen in either study.

Bupropion produced a positive response (two to three times control mutation rate) in two of five strains in the Ames bacterial mutagenicity test and an increase in chromosomal aberrations in one of three in vivo rat bone marrow cytogenic studies.

A fertility study in rats at doses up to 300 mg/kg revealed no evidence of impaired fertility.

Pregnancy: ***Teratogenic Effects: Pregnancy Category B:*** Teratology studies have been performed at doses up to 450 mg/kg in rats (approximately 14 times the MRHD on a mg/m^2 basis), and at doses up to 150 mg/kg in rabbits (approximately 10 times the MRHD on a mg/m^2 basis). There is no evidence of impaired fertility or harm to the fetus due to bupropion. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studie not always predictive of human response, this drug should be during pregnancy only if clearly needed. Pregnant smokers shoul encouraged to attempt cessation using educational and behav interventions before pharmacological approaches are used.

Labor and Delivery: The effect of ZYBAN™ on labor and delive humans is unknown.

Nursing Mothers: Bupropion and its metabolites are secreted in hu milk. Because of the potential for serious adverse reactions in nur infants from ZYBAN, a decision should be made whether to discont nursing or to discontinue the drug, taking into account the importanc the drug to the mother.

Pediatric Use: Clinical trials with ZYBAN did not include individ under the age of 18. Therefore, the safety and efficacy in a pedia smoking population have not been established. The immediate-rele formulation of bupropion was studied in 104 pediatric patients (range, 6 to 16) in clinical trials of the drug for other indications. Altho generally well tolerated, the limited exposure is insufficient to assess safety of bupropion in pediatric patients.

Use in the Elderly: In general, older patients are known to metabol drugs more slowly and to be more sensitive to the side effects of dru A single-dose pharmacokinetic study demonstrated that the disposit of bupropion and its metabolites in elderly subjects was similar to tha younger subjects (see CLINICAL PHARMACOLOGY section of prescribing information). Of the approximately 5,600 patients w participated in clinical trials with bupropion sustained-release tabl (depression and smoking cessation studies), 303 were 60 to 69 years and 88 were 70 years of age or older. The experience with patients years of age or older was similar to that in younger patients.

ADVERSE REACTIONS: (see also WARNINGS and PRECAUTIONS)

The information included under ADVERSE REACTIONS is based primarily data from the dose-response trial and the comparative trial that evaluat ZYBAN for smoking cessation (see CLINICAL TRIALS section of full prescribi information). Information on additional adverse events associated with t sustained-release formulation of bupropion in depression trials, as well as t immediate-release formulation of bupropion, is included in a separate secti (see Other Events Observed During the Clinical Development a Postmarketing Experience of Bupropion).

Adverse Events Associated With the Discontinuation of Treatmen Adverse events were sufficiently troublesome to cause discontinuation treatment in 8% of the 706 patients treated with ZYBAN and 5% of the 3 patients treated with placebo. The more common events leading discontinuation of treatment with ZYBAN included nervous system disturbanc (3.4%), primarily tremors, and skin disorders (2.4%), primarily rashes.

Incidence of Commonly Observed Adverse Events: The most common observed adverse events consistently associated with the use of ZYBA were dry mouth and insomnia. The most commonly observed advers events were defined as those that consistently occurred at a rate of fiv percentage points greater than that for placebo across clinical studies.

Dose Dependency of Adverse Events: The incidence of dry mouth an insomnia may be related to the dose of ZYBAN. The occurrence of thes adverse events may be minimized by reducing the dose of ZYBAN. I addition, insomnia may be minimized by avoiding bedtime doses.

Adverse Events Occurring at an Incidence of 1% or More Amon Patients Treated With ZYBAN: Table 1 enumerates selected treatment-emergent adverse events from the dose-response trial that occurred a an incidence of 1% or more and were more common in patients treate with ZYBAN compared to those treated with placebo. Table 2 enumerate selected treatment-emergent adverse events from the comparative tria that occurred at an incidence of 1% or more and were more common i patients treated with ZYBAN, NTS, or the combination of ZYBAN and NT compared to those treated with placebo. Reported adverse events were classified using a COSTART-based dictionary.

Table 1

Treatment-Emergent Adverse Event Incidence in the Dose-Response Trial*

Body System/ Adverse Experience	ZYBAN™ 100 to 300 mg/day (n = 461) %	Placebo (n = 150) %
Body (General)		
Neck pain	2	<1
Allergic reaction	1	0
Cardiovascular		
Hot flashes	1	0
Hypertension	1	<1
Digestive		
Dry mouth	11	5
Increased appetite	2	<1
Anorexia	1	<1
Musculoskeletal		
Arthralgia	4	3
Myalgia	2	1
Nervous system		
Insomnia	31	21
Dizziness	8	7
Tremor	2	1
Somnolence	2	1
Thinking abnormality	1	0
Respiratory		
Bronchitis	2	0
Skin		
Pruritus	3	<1
Rash	3	<1
Dry skin	2	0
Urticaria	1	0
Special Senses		
Taste perversion	2	<1

*Selected adverse events with an incidence of at least 1% of patients treated with ZYBAN and more frequent than in the placebo group.

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SMOKING
CESSATION
TREATMENT

FINALLY,
A NON-NICOTINE TABLET
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BIOLOGY OF NICOTINE ADDICTION

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ZYBAN is presumed to act on the dopaminergic (reward) and/or noradrenergic (withdrawal) pathways involved in nicotine addiction and withdrawal[1,2*]

ZYBAN helps reduce the urge to smoke[2]

ZYBAN helps reduce nicotine withdrawal symptoms

RGE TO SMOKE

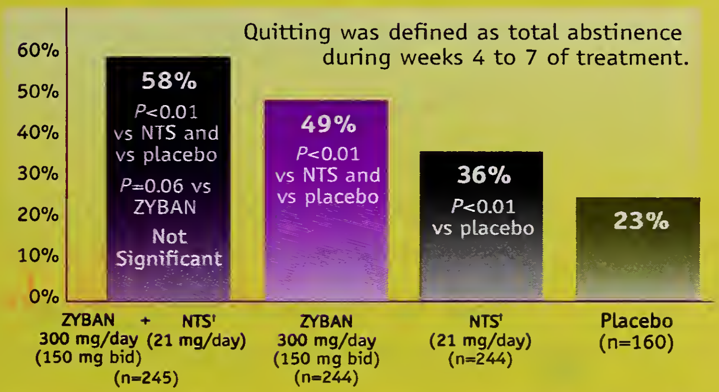
NEW

ZYBAN™

bupropion HCl sustained-release tablets 150 mg

NEUROCHEMISTRY. NOT NICOTINE.

Significantly higher 4-week quit rates than nicotine patch[†] in a 9-week[‡] comparative trial[2]



Data are from a multicenter, double-blind, placebo-controlled, parallel, randomized trial. All patients were administered either an active or a placebo tablet and wore either an active or a placebo patch. Patients received brief (5-10 minutes) individual smoking cessation and relapse prevention counseling.

[†] Habitrol® (nicotine transdermal system) (NTS) 21 mg/day. Ciba-Geigy Corp.

[‡] NTS therapy was initiated at the target quit day (days 8 to 14) and tapered at week 8 (14 mg/day) and at week 9 (7 mg/day). ZYBAN was not tapered.

Quit rates in clinical trials are influenced by the population selected. Quit rates in an unselected population may be lower than the above rates.

First-line therapy as an aid to smoking cessation treatment

- ZYBAN helps reduce nicotine withdrawal symptoms and the urge to smoke, presumably through neurochemical pathways.[2]
- Patients start ZYBAN 1 to 2 weeks before their target "quit day"... unlike nicotine replacement therapy.
- For the remainder of 7 to 12 weeks of therapy, ZYBAN provides pharmacological treatment along with individualized patient support, the ZYBAN Advantage Plan™.
- This plan should be part of a comprehensive smoking cessation treatment program to help your patients' chances of success.

Adverse event profile: Most common adverse events were dry mouth and insomnia.

*Studies were conducted in animal models. The mechanism of action is unknown.

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How to conveniently prescribe ZYBAN

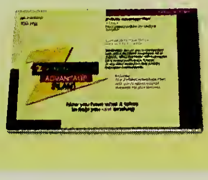
Dosing should begin at 150 mg/day for the first 3 days.

Increase dosage to the recommended and maximum 300 mg/day (150 mg bid) for most patients for 7 to 12 weeks.* Allow at least 8 hours between successive doses.

MONTH 1

RX OPTION 1

Dispense ZYBAN Sample Pack:
Contains first 3 days of therapy and the ZYBAN Advantage Plan™ (Available only from your Glaxo Wellcome representative)



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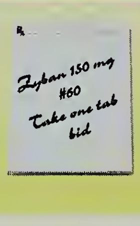

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Zyban 150 mg
#60
Take one tab
bid

OR

RX OPTION 2

Write Rx for ZYBAN Advantage Pack™:
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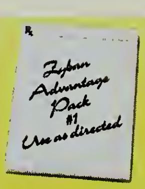

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Advantage
Pack
#1
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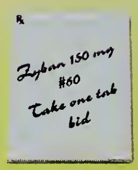
MONTHS 2 TO 3



℞
Zyban 150 mg
#60
Take one tab
bid

Write Rx
for ZYBAN
Tablets
150 mg bid
#60

*Clinical data are not available on the long-term use (>12 weeks) of bupropion for smoking cessation.

ZYBAN is contraindicated in patients with a seizure disorder or with a current or prior diagnosis of bulimia or anorexia nervosa. The concurrent administration of ZYBAN Tablets and an MAO inhibitor is contraindicated.

ZYBAN contains the same active ingredient found in WELLBUTRIN® and WELLBUTRIN SR® used to treat depression, and should not be used in combination with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion.

The use of bupropion is associated with a dose-dependent risk of seizures. Therefore, *clinicians should not prescribe doses over 300 mg/day for smoking cessation*. The risk of seizures is also related to patient factors, clinical situation, and concurrent medications, which must be considered in selection of patients for therapy with ZYBAN.

Please consult brief summary of Prescribing Information on next page.

Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 FEBRUARY 1998 NUMBER 2

scientific:

Muhammad Wasif Saif, Edward E. Morse,
a 67 **HIV-Associated Autoimmune Hemolytic Anemia Complicated by Pulmonary Embolism Following a Red Blood Cell Transfusion: Case Report and Review of the Literature**

Elihu Y 71 **Noxious Fumes in a Medical Center: Chemical and Psychological Aspects**

Dona
Paul B
Jay H 75 **Clinical Evaluation of Hand-arm-vibration Syndrome in Shipyard Workers: Sensitivity and Specificity as Compared to Stockholm Classification and Vibrometry Testing**

Drug Information Update: Hartford Hospital
85 **Remifentanil (Ultiva™)**

Mark L.
Michael A. F
Leslie Isr 89 **A Community Hospital's Ambulatory Addiction Medicine Program**

y 95 **Why Not to Invest in a Publicly Traded Managed Care Company**
s 96 **"Slow Down, You Move Too Fast"**

Arnold S. Relman 97 **The Corporatization of the United States Health-care System**

departments:

Fifty Years Ago
99 **Personality and Practice**

The President's Page
Stanley J. Keating, Jr. 101 **An Alternative from the Midwest**

Reflections on Medicine
Robert U. Massey 103 **What About Character?**

Medical News Capsules
Timothy B. Norbeck 105 **This Month's Reading in Review**

Letters to the Editor
Edward J. Volpintesta 106 **Should the City Medical Societies Take an Active Part?**
Henry N. Blansfield 106 **In Response to *Physician Assisted Living (PAL)***
Morris A, Wessel 107 **In Response to *the Physicians Assisted Living: The PAL Partner Initiative* Article**
rikangas, Robert C. George, and Charles W. Needham 108 **In Response to Dr. Maria Lenaz's *Letter to the Editor* "Ethics in Managed Care"**
Christopher Randolph 109 **In Response to Dr. Richard Evans's *Update on Childhood Asthma***

From the Executive Director's Office
111 **Council Meeting**

general:

121 **CSMS Physician Placement Service**

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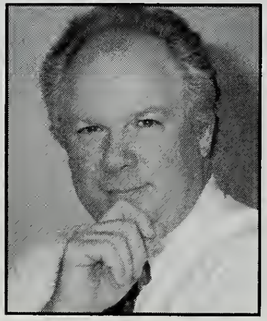

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HIV-Associated Autoimmune Hemolytic Anemia Complicated by Pulmonary Embolism Following a Red Blood Cell Transfusion:
Case Report and Review of the Literature

MUHAMMAD WASIF SAIF, M.D., EDWARD E. MORSE, M.D.,
AND BERNARD R. GREENBERG, M.D.

ABSTRACT—*Background:* Though positive direct antiglobulin tests are common in AIDS patients, overt hemolysis is rare. A hypercoagulable state has recently been recognized in these patients and may contribute to the thromboembotic complications previously reported in three patients with HIV-associated autoimmune hemolytic anemia.

***Case report:* An AIDS patient with severe warm autoimmune hemolytic anemia developed a pulmonary embolus after a single red blood cell transfusion.**

***Conclusion:* There may be an increased risk of thromboembolism in AIDS patients with autoimmune hemolytic anemia who receive red blood cell transfusions, a concern we have previously raised.[1] Prophylactic anticoagulation should be considered in this setting.**

Introduction

AIDS may lead to a variety of hematological abnormalities including anemia, thrombocytopenia, leukopenia, bone marrow dysplasia, autoimmune hemolysis, and hypercoagulability.[2,3] Several studies have documented a high incidence of positive direct antiglobulin tests (DATs) in AIDS patients[4,5] but overt hemolysis is a rare complication. The recent literature contains reports of thrombotic events in AIDS patients who had none of the clear-cut predisposing factors that result in hypercoagulability.[6-9] Bilgrami et al reported an unusual case of a patient who at the time of presentation with severe AIHA was found to be HIV positive.[1] Shortly thereafter, he developed disseminated intravascular coagulopathy, pulmonary thrombi, and right ventricular failure following red blood cell transfusions, and expired in spite of intensive supportive measures. We now report another case of severe warm autoimmune hemolytic anemia in a patient with AIDS who subsequently developed a pulmonary embolus after a red blood cell transfusion. This case emphasizes the need to consider thromboembolism in AIDS patients with autoimmune hemolytic anemia despite their young age. It provides a rationale for further studies to elucidate the increased risk of thromboembolism in HIV-associated autoimmune hemolytic anemia with or without red blood cell transfusions. This case also raises an important question which needs to be addressed: "Do patients with HIV-associated autoimmune hemolytic anemia need anticoagulation when transfused?"

Abbreviations Used in Text

DAT = direct antiglobulin test
AIDS = acquired immune deficiency syndrome
AIHA = autoimmune hemolytic anemia
HIV = human immunodeficiency virus

Case Report

The patient is a 32-year-old Afro-American male with advanced AIDS (CD4 count, 80) acquired through unprotected bisexual exposure. He was admitted in August 1996 because of shortness of breath secondary to anemia. His past medical history is significant for nephrotic syndrome secondary to HIVnephropathy, first documented in April 1995, and autoimmune hemolytic anemia responsive to corticosteroids, diagnosed in February 1996.

MUHAMMAD WASIF SAIF, M.D., third-year residient, primary care internal medicine, University of Connecticut School of Medicine; EDWARD E. MORSE, M.D., professor of laboratory medicine, University of Connecticut School of Medicine; BERNARD R. GREENBERG, M.D., interim chief, Division of Hematology/Oncology, professor of medicine, Department of Medicine and Department of Laboratory Medicine, University of Connecticut School of Medicine, Farmington.

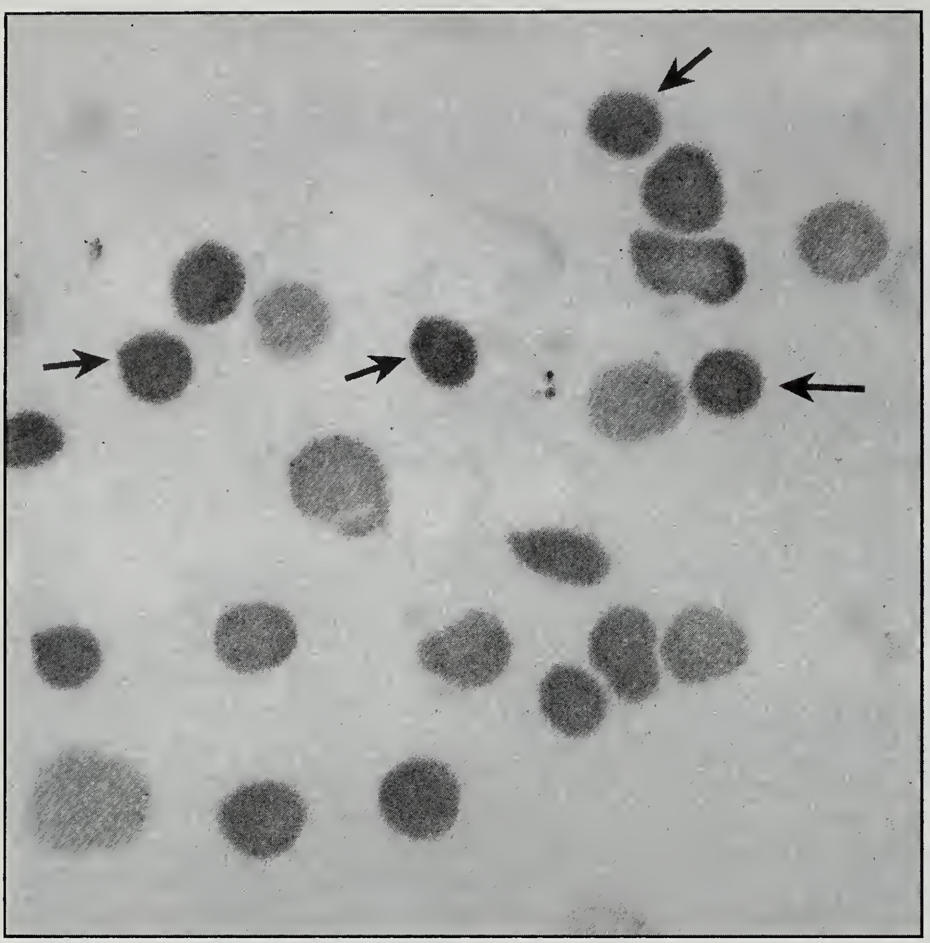

Figure 1.—Peripheral blood smear demonstrating prominent spherocytosis (arrows) consistent with active autoimmune hemolysis (x 1000).

The patient's hematocrit was 41% in May 1996, but decreased gradually over the subsequent months to 17%. Physical examination revealed stable vital signs, marked pallor, mild hepatomegaly, and no splenomegaly.

The laboratory findings included hemoglobin, 7.1 g/dL; hematocrit, 17%; white blood cell count, 5,900/cu mm; platelet count, 523 X 10^3 cu mm; mean corpuscular volume, 106 FL; reticulocyte count (uncorrected), 13.2%; lactate dehydrogenase, 534 U/L (normal 81–175 U/L); total bilirubin, 0.4 mg/dL; direct bilirubin, 0.2 mg/dL; alanine aminotransferase,52 U/L; asparate aminotransferase, 67 U/L; albumin, 2.1 g/dL; alkaline phosphatase, 125 IU/L (normal 39–113 IU/L); blood urea nitrogen, 65 mg/dL (normal 8–24 mg/dL); creatinine, 6 mg/dL (normal 0.61.2 mg/dL); and a positive direct Coomb's test. The peripheral smear revealed prominent spherocytosis, (Fig. 1) microcytosis, macrocytosis, basophilic stippling, and polychromasia. Iron, B_{12}, folate, and erythropoietin levels were all normal. A warm IgG antibody was detected in his serum; no cold agglutinins were present; his cells were found to be coated with C3; and titers for mycoplasma and parvovirus B19 were negative. Following differential adsorption at 37°C using R_1R_1, R_2R_2, and rr reagent red cells, anti-Jk^b was demonstrated in addition to the autoantibody.

The patient was treated with prednisone (first 60 mg daily then 100 mg daily) but his shortness of breath persisted and his hematocrit continued to drop. Intravenous IgG was then administered without improvement in the hematocrit. Because of increasing shortness of breath associated with mild acidosis, a decision was made to transfuse one unit of the least incompatible Jk^b (–) red blood cells cautiously. He tolerated this transfusion, which slightly raised his hematocrit. Two days posttransfusion, he became more short of breath. Arterial blood gases revealed severe hypoxemia and a ventilation-perfusion lung scan manifested a moderate probability for pulmonary embolus. The patient was then treated with intravenous heparin and discharged on oral warfarin. His hematocrit steadily rose to 36% while still receiving large doses of prednisone (100 mg daily).

Discussion

Three patients with HIV-associated autoimmune hemolytic anemia resulting in thromboembolism have been previously described in the literature.[1,10,11] We now report another case suggesting an association between HIV-associated autoimmune hemolytic anemia and thromboembolic phenomenon.

The mechanism by which HIV-infected patients develop autoimmune hemolytic anemia remains unclear. Several mechanisms have been postulated including a causal association between hypergammaglobulinemia and positive direct antiglobulin tests (DAT) such that overabundant IgG adheres to red blood cells resulting in DAT positivity;[12] immune-complex-associated IgG which adheres to red blood cells via C3b receptors rather than via autoantibodies directed against red cells;[13] Evan's syndrome (immune thrombocytopenia with concomitant hemolytic anemia);[14] or an association with infectious agents eg, *Mycoplasma avium intracellulare*, cytomegalovirus, *Pneumocystis carinii, mycobacterium tuberculosis, histoplasma capsulatum,* or related to malignant lymphoma.[14-18]

The clinical presentation may vary from a mild form with the only finding being a positive DAT, to a moderate anemia with splenomegaly, to fulminant hemolysis with marked spherocytosis in the most severe forms. The serological findings in AIDS are variable including coating of erythrocytes by IgG and C3 both, or IgG alone. In addition, the simultaneous presence of both cold and warm autoantibodies has been reported to be more common in HIV-associated autoimmune hemolytic anemia than non-HIV.[19]

Glucocorticoids (prednisone, 1.0 mg/kg/day) remain the mainstay of therapy.[14] This may slow or stop the hemolysis in two-thirds of patients and a response with an increased hemoglobin within the first week is usually seen. After the hematocrit stabilizes, a slow taper of steroids may be initiated. Variable rates of success have been achieved with intravenous immunoglobulin and, in a few cases, administered together with corticosteroids.[14,20] Splenectomy is indicated in patients in whom steroids cannot be tapered, or who demonstrate an inadequate response to steroids with persistent severe anemia.[14] A success rate of about 75% has been reported for splenectomy, a rate not much different from that found in non-HIV autoimmune hemolytic anemia. The role of immmosuppressive agents is not generally accepted and plasmapheresis remains controversial. Since the autoantibodies behave as polyagglutinins reacting with all normal donor cells, this interferes with the usual crossmatching procedure and increases the likelihood of transfusion-induced complications. Therefore, it is not advisable to transfuse patients except in emergency situations.[1]

HIV-associated autoimmune hemolytic anemia has been associated with an increased risk of thromboembolism, particularly during the active period of hemolysis, thus complicating an already difficult clinical situation.[1,10,11,21] The pathophysiology for these thrombo-emblolic events has not been established. Various abnormalities consistent with a hypercoagulable state have been reported in AIDS patients and correlate with the severity of HIV-related immunosuppression (CD4 cell count). and the presence or absence of infectious or neoplastic diseases.[21-24] Such abnormalities include circulating antiphospholipid antibodies (lupus anticoagulant)[25-26] decreased levels of functional protein C as well as low protein C antigen,[24] deficiency of protein S and an increase in total protein S antigen,[24,27-29] deficiency of heparin cofactor II,[35] high levels of Von Willebrand's factor,[24] and increased levels of d-dimers.[24] Several investigators have noted that thromboembolic episodes occurred most commonly in AIDS patients in whom the albumin level was less than 3 g.[31] They suggested that malnutrition results in decreased liver production of proteins including antithrombin III, predisposing to a relative hypercoagulable state. In our case, the nephrotic syndrome secondary to HIV nephropathy could result in antithrombin III deficiency.

Management of thromboembolic events in HIV-infected patients is similar to non-HIV patients and includes anticoagulation and prophylaxis in cases of recurrent thrombosis. Also careful monitoring of the coagulation profile is required because of thrombocytopenia and drug-interactions such as with rifampicin.

It is possible that red cell transfusions in HIV-infected patients with severe AIHA may potentiate the hypercoagulable state sufficiently to produce occlusion of an already compromised pulmonary vascularity. Consideration should be given to prophylactic anticoagulation in this setting, if there are no major contraindications.

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The authors thank Joyce Fritz and Joe Pallis for their invaluable assistance in manuscript preparation.

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Noxious Fumes in a Medical Center: Chemical and Psychological Aspects

ELIHU YORK, M.D., MICHAEL J. HODGSON, M.D.,
BRIAN W. COOPER, M.D., AND CHARLES A. McKAY, JR., M.D.

ABSTRACT—A group of operating room personnel at a medical center in Connecticut reported severe respiratory irritation manifested by either proxysmal cough or throat irritation suggestive of a noxious fume exposure, 13 April 1994. However, persistent complaints on 14 April 1994 were significantly different and more suggestive of a psychological reaction. By careful interviewing, physical examination, toxicological assays, and epidemiological investigation, the true nature of a mixed physiological and psychological episode was delineated. Enlightened management policy enabled rapid restoration of return to work with minimal economic loss.

Introduction

OUTBREAKS of disease related to buildings have been recognized with increasing frequency since the 1980s.[1,2] Mucous membrane irritation, central nervous system symptoms, and other symptoms that may occur in between 8% and 60% of office workers are attributed to mechanical ventilation systems, complex mixtures of volatile organic compounds, and bioaerosols.[3-8] An association with work stress is commonly recognized.[9,10] Most authors agree that "sick building syndrome" phenomena do not represent mass psychogenic illness (MPI).[11-14] Perception of discomfort does not automatically represent disease.

Outbreaks of MPI have been reported, which in some instances may represent work stress, with loss of work time and some degree of economic loss.[15,16] Public health practice relating to adolescents with MPI often relies on simply ignoring the problem.[17-22] Many health professionals have advocated a similar strategy regarding MPI in the workplace without recognizing the difference between transient psychological disturbance, suggestibility of adolescence, and stress in the workplace.[23-26] If stress is the cause of MPI in the workplace, the appropriate intervention strategy must rely on organizational intervention.[27] The authors present a cluster of symptoms related to an irritant and a follow-up evaluation that allowed resumption of normal activities.

History of Exposure

On 13 April 1994, a group of operating room employees at a medical center in Connecticut reported severe respiratory irritation manifested by paroxysmal cough or throat irritation consistent with noxious fume exposure.

At 3:25 P.M. on 13 April 1994, a mist was either felt or seen by several employees in the hospital's main operating suite women's locker room. The first affected individual noted a burning sensation in throat and chest areas, followed immediately by a syncopal episode. Anesthesiologists at the scene provided assisted ventilation to the subject for what was described as near-respiratory arrest! Other employees had symptoms as detailed below. A total of 18 employees were sent to the hospital's emergency center for evaluation. All were discharged later the same evening. Several other employees reported to the emer-

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gency center between 11:00 and 12:00 P.M. on 13 April, and were discharged within an hour. On the morning of 14 April, recurrent symptoms developed in employees during a previously scheduled, but prolonged, electrical shutdown to test the auxiliary generators. Twenty-five individuals later reported during the morning and early afternoon for interviews and examinations at the Employee Health Service's ambulatory clinic, while several others went directly to the emergency center. One individual reported a respiratory complaint on 15 April.

Methods

A detailed questionnaire was developed and administered to a total of 50 employees who had reported any type of discomfort. Although there was some overlap of symptoms both on 13 and 14 April, there were some distinct differences particularly for those reporting on 14 April. The frequency and type of symptoms analyzed by the epidemiologists were stratified by date, and then were compared using the Mantel–Haenszel X^2 test.

There was a statistically significant difference noted for some symptoms:

- Paroxysmal cough and throat irritation were more common on 13 April.
- Cough was present in 19 of 24 (79%) of exposed individuals, in contrast to only seven of 25 (28%) on 14 April ($P = 0.0003$, relative risk 2.83).
- Throat irritation was common on 13 April, with 20 of 24 individuals (83%) exposed reporting throat irritation *vs* 14 of 25 (56%) on 14 April ($P = 0.039$, relative risk 1.49).
- Four symptoms were common on 14 April, eye irritation, dysgeusia (taste discomfort), palpitations, and numbness.
- Eye irritation was present in 10 of 25 (40%) individuals exposed on 14 April, in contrast to only one of 24 (4.2%) on 13 April ($P = 0.003$, relative risk 0.1). Taste discomfort was reported in 10 of 25 (40%) exposed 14 April, compared to only two of 24 (12.5%) individuals exposed on 13 April ($P = 0.03$, relative risk of 0.32). Although not statistically significant, a trend toward increasing prevalence on 14 April was noted for both palpitations and numbness ($P = 0.13$ and 0.19 respectively).

The location of employees at the onset of symptoms was around both the female locker room and the employee lounge. The shaded area on the floor plan (Fig. 1) diagram indicates where 20 of 24 (83%) of all exposures occurred on 13 April. During 14 April, five of 25 (20%) of the exposures occurred in the lounge / locker room area ($P = 0.0001$). There were other exposures on 14 April, spread throughout other areas of the hospital, such as the cafeteria, main building 4th floor (separate from the operating room suites on that floor), recovery room, ambulatory surgery suite, other operating rooms, nonoperating room areas, and even at home!

Exposure Analysis

The outbreak was reported promptly to the security department. The initial investigation was conducted by the safety manager, the hospital's fire marshall, and later by members of the city fire department and two commercial firms specializing in environmental remediation. Upon leaving the operating room suite, employees were requested to submit any personal protection cannisters (mace) for inspection by security officials. Each cannister appeared unused. Air quality meters and Drager tubes testing for oxides of nitrogen, ozone, and other irritants were unrevealing for detectable limits of any harmful gas.

Environmental firm #1 responded promptly on 13 April. Utilizing portable gas detector sampling devices (including charcoal and Tenax tubes, and passive organic vapor monitoring badges) the consultant found no chemical concentrations to explain the immediate discomfort experienced by the employees. Their final results were reported on 20 April. Environmental firm #2, called on 14 April, tested for volatile organics, but found no detectable contaminants from samples obtained that day. The results were reported on 15 April.

An industrial hygienist from the Occupational Safety and Health Administration (OSHA, Connecticut office) obtained wipe samples on the afternoon of 14 April; subseqeuently, those samples were analyzed at a laboratory in Utah on 20 June. The OSHA report was forwarded to the hospital on 19 August, indicating that 1.68 *m*g of capsaicin (pepper spray) was present at time of sampling (14 April). The detection (lower) limit for capsaicin = 1 *m*g.

Following the exposure of many operating room personnel, both on the evening of 13 April and the morning of 14 April, the entire operating room suite was closed for 24 hours, precluding performance of any further procedures. On the morning of 15 April, between the hours of 6:00 A.M. and 7:00 A.M., 49 of the exposed individuals were evaluated by a team comprising physicians and nurse practitioners from the employee health service, epidemiology department, and emergency center. Detailed symptom questionnaires were completed by the affected employees. When most of the employees were found "fit for duty," the operating room scheduled procedures were resumed, beginning at 7:30 A.M. on 15 April.

Discussion

Although the epidemiological analysis of the exposure was incapable of identifying the precise nature of the vapor release that had occurred on 13 April, several relationships became clear as the data were analyzed. There was no question that a large number of employees was exposed on 13 April to a respiratory irritant. Symptoms were mainly throat irritation and paroxysmal cough. The brief initial exposure appeared to have an epicenter originating in the female locker room which did not spread to other areas of the operating room suite.

On 14 April, the following morning, a similarly large group of hospital employees developed a set of symptoms primarily characterized by eye irritation, abnormal taste, palpitations, and numbness. A few of the employees also developed throat irritation and cough. There was no epicenter for the 14 April exposure, with symptomatic individuals scattered throughout the operating room and adjoining areas.

An explanation for the symptoms reported on 14 April includes a combination of anxiety, suggestion, and possibly wash-out effects from the severe irritant exposure the previous day. The timing of an electrical outage (a previously scheduled emergency drill) was most unfortunate! Frequently noted symptoms of eye irritation and bad tastes the second day (14 April) could have been attributed to the lack of air circulation, resulting in stagnant, stale air within the locker room and bathroom area, as well as other areas in the hospital. The resultant focus on odor and taste, after reflecting on the previous day's episode, led to a diagnosis consistent with anxiety and hyperventilation.

Several group meetings with exposed employees included concerned medical and nurse-practitioner staff from employee health service, emergency center, and the epidemiology division; these allowed employees to voice concerns and have their questions answered in open forum. Although hindered by incomplete chemical data at the time (14 April); we nevertheless felt that group meetings, as well as individual counseling sessions, were important in preventing further episodes of "dis-ease." Subsequent surveillance of operating room employees after 15 April revealed no recurrent symptoms. Environmental monitoring revealed no persistent or recurrent hazards. The source for the original fumes or mist (later proven to be capsaicin, (pepper spray), was never established.

The medical center's management strategy differed from the simplistic approach of denying the presence of disease. A primary reason for more intensive follow-up and scrutiny was the potential loss of personnel by visits to the occupational health service or the shutting down of operating rooms again, which would have led to much greater disruption and economic loss.

There are lessons to be learned from an episode wherein "minor symptoms" are interpreted as disease. In situations where there are few physical findings, the symptoms are often attributed to "psychogenic illness," usually with pejorative connotation.[9] In actuality, physical findings, sparse though they may be, in conjunction with the symptoms, when corroborated by laboratory testing, epidemiological analysis, and clinical evaluation substantiate that both physical and psychological factors are important![13] The variety of symptoms on the second day indicated the psychological rather than the chemical aspects.[14,15] Several weeks passed before the report of the specific chemical was available, although capsaicin had been suspected from the outset.

Other investigators have noted occurrences involving both physical and psychological components, whereby individuals exposed had varied complaints.[17-22] Reports from schools, chemical plants, community centers, aerospace manufacturing, medical centers, and telecommunications all have contributed examples of the problem of differentiating the various factors which lead to absenteeism, lost productivity, and illness claims.[10-12,14-16,22,24-27]

Conclusion

Recognizing both chemical and psychological aspects of the noxious fume exposure served to integrate these into a uniform objective of restoring employees expeditiously and safely to the workplace. Because of the strong human resource program at the medical center, the approach taken by physicians, nurses, epidemiologists, safety professionals, and engineers investigating the outbreak demostrated consideration for exposed employees and their concerns.

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Clinical Evaluation of Hand-arm-vibration Syndrome in Shipyard Workers: Sensitivity and Specificity as Compared to Stockholm Classification and Vibrometry Testing

DONALD C. KENT, M.D., RODNEY ALLEN, PH.D., PAUL BUREAU, M.S., MARTIN CHERNIACK, M.D., JAY HANS, M.S., AND MYRON ROBINSON, PH.D.

ABSTRACT—The hand-arm-vibration syndrome (HAVS) is a complex entity composed of circulatory, sensory, and motor disturbances, as well as associated musculoskeletal components. This study was performed to find a diagnostic testing modality with sufficient sensitivity, specificity, and predictive value to be utilzed as a screening test for this disorder in a working population. A full range of testing modalities was utilized in the shipyard medical department. In addition, a clinical diagnosis of vascular and sensorineural disease was established in the workers by a combination of plethysmography, vibrometry, two point discrimination, and monofilament testing in an independent occupational medicine clinic. No one test modality met the requirements for such a definitive diagnostic test. Rather, a range of modalities was required to reach any acceptable level of predictive value, with sufficient degrees of specificity and sensitivity.

Introduction

THE hand-arm-vibration syndrome (HAVS) has been known since the early 1900s, but better defined in 1983 by scientists at an international conference in London as being composed of three components: circulatory disturbances, sensory and motor disturbances, and musculoskeletal symptoms.[1] Dr. Alice Hamilton, as early as 1918, examined a group of stonecutters and carvers at the limestone queries in Bedford, Indiana, and described the clinical aspects of this disorder.[2] In a 1983 NIOSH publication some 1,246,000 workers were considered to be exposed to hand-arm vibration in the United States, particularly in the following industries: construction, farming, metal working, steel, lumber, wood, furniture manufacturing, mining, truck and auto manufacturing, and foundries.[3] Since that time, the number of involved industries has increased and has included a number of other industries, including shipyards.[4-6] Various publications,[7-9] including Palmear, Taylor, and Wasserman's textbook[7] have outlined the clinical evaluation of patients with HAVS. One clinical study of neurological function in shipyard workers was reported by Cherniack et al in 1990.[10] Few, however, have made an attempt to evaluate the sensitivity and specificity of the testing modalities in such evaluations. One essential problem with specificity testing has been that it assumes a gold standard case definition in addition to symptoms, and thus the attendant problem accepting such a standard.

In a shipyard setting, rising subjective complaints of HAVS among workers and increasing workers' compensation costs led to a management-labor decision to develop a program for early detection and prevention of HAVS in the shipyard. An initial effort was directed toward the measurement and identification of the cause of excessive vibration in production hand tools and a view toward engineering the vibration to safer levels and/or the use of protective antivibration gloves and materials. In addition, a second effort was made to find medical tests that were predictive of changes in the worker's response

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to surface vibration and that could be efficiently utilized in the shipyard setting. These tests had to be sensitive enough to identify early deleterious effects in vibration sensitivity secondary to vibration, but also cost effective and simple enough to be performed in the shipyard setting. Research in Scandinavia had focused on a psychophysiological vibrometer as a quick but accurate indicator of vibration-induced trauma in quarry and forestry workers who used vibratory tools.[11] This experimental protocol was thus established to assess this unit's accuracy in predicting the onset of early HAVS and in providing secondary diagnostic information on employees already exhibiting HAVS symptoms. As a part of the study, each worker received a HAVS clinical evaluation in the shipyard medical department. This report deals with the results of these clinical evaluations in such a clinical setting as viewed against the vibrometry results and the symptomatology as measured by the Stockholm Workshop Scale, as well as the more detailed diagnostic investigations performed in the independent occupational medicine clinic (Martin Cherniack).

Methods

The subjects for the study consisted of 10 control employees who had received no exposure to vibration in their shipyard employment and 40 workers assigned to the grinding department, each with varying levels and periods of vibration exposure, all working as full-time users of grinding tools. Two were excluded from the study because of insufficient test data.

Each employee received an extensive life and work history and symptom questionnaire. This was graded according to the Stockholm Workshop Scale for both vascular and sensorineural stages of symptoms separately by three evaluators, one an occupational medicine physician, the other two industrial hygienists with extensive experience in ergonomics. The results of these three evaluations were collated, resulting in the vascular and sensorineural staging.

The clinical examination consisted of a general physical examination of both upper extremities, measurements of wrist flexion and extension, metacarpal flexion and extension, all by goniometry, noting the dominant hand for each examinee. In addition, radial and ulnar lateral wrist motion was determined. Clinical vascular examination of both extremities consisted of the following: Adson's test (neck extension, chin rotation to the side, and deep breath holding), Allen's test (compression of radial and ulnar arteries, with raising of the hand, opening and closing of the fist, and release of pressure on the radial artery, watching for flush time), and the Lewis Prusik test (10 second pressure on the nail bed and observing recovery time upon release of pressure). Radial arterial pulses were examined bilaterally with the following maneuvers: hyperabduction, costoclavicular, and abduction with external rotation. The following physical examination findings were considered abnormal: wrist flexion less than 80 degrees, wrist extension less than 60 degrees, metacarpal flexion less than 80 degrees, metacarpal extension less than 15 degrees, ulnar lateral wrist mobility less than 45 degrees, and ulnar lateral wrist mobility less man 15 degrees. The Lewis Prusik test was considered abnormal when recovery time was in excess of five seconds. Adson's and Allen's tests were reported as positive or negative, as were hyperabduction, costoclavicular, and abduction external rotation maneuvers: positive test results were considered abnormal.

Clinical sensorineural measurements of both extremities as utilized in the evaluation are listed in Table 1 and included the following: gross grip strength measured by a Jamar™ hand grip dynamometer. Tip (two-point), key (lateral) and palmar (chuck) pinch indices were measured by a Jamar PC 5930 hydraulic pinch gauge. All measurements were made twice and the average taken as the reported value. The normative data of Mathiowetz et al[13] was utilized in determining normal values for these hand strengths. Variances in excess of the standard deviation for each test were considered as abnormal.

Cutaneous two-point discrimination was measured utilizing a Lafayette Instrument Company #16011 anesthesiometer on the right and left third and fifth digits. Abnormal two-point discrimination was defined as inability to detect a gap of 7 mm or more. Light touch sensitivity was evaluated with Semmes-Weinstein monofilaments, reported as filament size, filament 2.83 considered as normal, 3.61 as diminished light touch, 4.31 diminished protective sensation, 4.56 loss of protective sensation, and 6.65 deep pressure only. Sensitivity was tested on both extremities, utilizing the third and fifth digits. Monofilament results were reported as the lightest monofilament sensitivity elicited response, 2.83 considered as normal, 3.61 as diminished light touch. Tinel's and Phalen's test were performed on each extremity, positive test results considered abnormal. Fine motor coordination was measured by a finger manipulation test requiring threading a series of nuts down threaded rods, the nuts and rods of different sizes, to test finger dexterity. Normal values for the test were taken as the mean value for the right and left hands of the control group.

All the clinical testing was performed by one occupational medicine physician to prevent examiner variance error.

Vibrotactile sensitivity thresholds were determined to seven frequencies, 8, 16, 32, 63, 125, 250, and 500 Hz respectively, utilizing the Model 9627 Bruel and Kjaer (B and K) vibrometer, testing performed on the dominant hand, third finger, as described by Lundborg et al.[11] For

Table 1.—Clinical Test Results

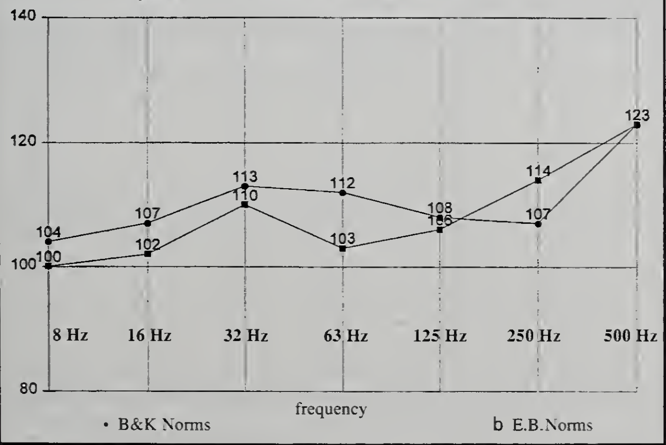
	C	V0	V1	V2	V3	SN0	SN1	SN2	SN3
Adson's	0	0	0	0	0	0	0	0	0
Allen's	0	0	1	1	0	0	2	0	0
Lewis Prusik	0	1	0	0	0	1	0	0	0
Hyperventilation	0	2	2	4	3	1	4	1	5
Costoclavicular	0	2	1	2	2	2	1	0	4
Abduction external rotation	0	3	0	1	1	1	1	1	2
Tinel	5	2	2	3	2	2	1	1	5
Phalen	1	1	2	2	2	1	1	1	4
Abnormal right dexterity	3	0	1	1	2	0	0	1	3
Abnormal left dexterity	3	5	4	5	2	2	3	3	8
Grip right	0	4	0	0	3	1	2	1	3
Grip left	0	0	1	0	2	0	2	0	2
Tip right	0	0	1	1	2	0	2	0	2
Tip left	0	2	1	0	3	0	3	0	3
Key right	0	7	1	4	3	0	5	3	4
Key left	0	3	1	4	3	0	3	2	6
Palmar right	2	8	3	5	4	2	8	4	6
Palmar left	2	6	4	3	6	2	6	3	10
Right two-point discrimination	1	3	1	2	1	1	2	0	4
Left two-point discrimination	1	0	0	1	2	0	0	0	3

C=Control

this study, vibrometry threshold measurements were considered abnormal when they were in variance from the threshold data supplied by B and K from the original study (Fig. 1). All control subjects tested below this level except for one unexposed subject who was a 62-year-old male who had multiple abnormal physical examination findings. The results of the vibrometry threshold testing are not reported in detail in this report but will be presented in a statistical analysis in a separate report.

The clinical diagnosis of both vascular and sensorineural disease was established by a combination of plethysmography, single frequence vibrometry, two point discrimination, and monofilament testing by an independent examiner (Martin Cherniack). The stage of disease in his classification was as follows: "0" for asymptomatic, "1" for mildly-moderately symptomatic (Stockholm Stage 2) and "2" as strongly symptomatic (Stockholm Stage 3 or 4).

Figure 1.—Normative Threshold Values



Results

Control Group.—The control group consisted of 10 shipyard employees with no history of contact with vibratory tools at work or in nonwork settings. The group comprised three females and seven males.

Exposed Group.—The vibratory tool exposed group consisted of 38 grinders, 37 males and 1 female. The age distribution was as follows: 10% age 21-30, 47% age 31-40, 32% age 41-50, 8% age 51-60, and 3% 61 and over. Seventy-one percent were Caucasian, 13% white Hispanic, 13% African-American, and 3% Native American. Years of exposure to vibratory tools were as follows: 5%, 0-10 years; 34%, 11-13 years; 49%, 14-16 years; 9%, 17-19 years; and 3%, 20-22 years. Fifty-three percent of the group were smokers at the time of the study. All of the group gave a history of using a vibratory tools at the time of the study. Nineteen were assigned to the first shift, 16 to second shift, and three to third shift.

Stockholm Classification.—Of the control group, two were classified as 1 sensorineural, one a 45-year-old female and the other a 67-year-old female. One was classified as 2 sensorineural, a 63-year-old male. None were classified other than 0 for vascular.

The results of the Stockholm Classification is shown in Table 2. It is noted that a significantly higher percentage presented with sensorineural symptoms as compared to vascular, and that the degree of severity of symptoms was significantly greater for the sensorineural symptoms. In eight, vascular and sensorineural classification was at the same level; in three vascular was greater than sensorineural, in 27 sensorineural was greater than vascular. These differences may be due to the staging process rather than actual prevalence, and may not be significant.

Physical Examination.—The results of the physical examination of the hands is noted in Table 3. It is evident that only four of the exposed group had normal findings on examination of the hands, whereas the examination was normal in nine of the control group. The most common finding was that of erythema of the terminal digits, noted in 11 of the vascular asymptomatic group (V0) and four of the sensorineural asymptomatic group (SN0). Twelve of the vascular (V1-V3) and 23 of the sensorineural (SN1-3) Stockholm group presented with erythema of the terminal digits. If one took the highest level of Stockholm classification, either vascular or sensorineural, the results were as follows: four were classified as 0, eight as 1, and 18 as 3.

Examination of the extremity mobility revealed only sporadic abnormality, and these abnormalities appeared in no specific pattern.

Similarly, the four vascular maneuvers presented with no specific pattern (Table 1) with the exception of hyperabduction, which was positive in nine of the V1-3 group and 11 of the SN1-3 group. This finding is possibly significant and merits further investigation. None of the maneuvers was positive in the control group.

The Tinel test was positive in five of the control group (Table 1), nine of the V0-3 group and nine of the SN0-3 group. The largest number of positives occurred in the SN3 group. The Phalen test as well as the Finkelstein test was positive in one control subject, the Phalen was positive in seven V0-3 and SN0-3 groups, with no consistent pattern related to symptom severity. The Finkelstein test was also positive in seven of the V0-3 and SN0-3 groups.

Table 2.—Stockholm Classification

	Number	**Percent**
V0	14	36%
V1	6	16%
V2	15	40%
V3	3	8%
V4	0	
SN0	5	13%
SN1	10	26%
SN2	5	13%
SN3	18	48%

Abnormal dexterity (Table 1) was considered abnormal in only sporadic workers in the right hand, whereas for the left hand, three of the control group were abnormal, 16 of V0-3 and SN0-3 were abnormal, with the largest number noted in the SN3 group.

Abnormal grip and tip grip measurements (Table 1) were only sporadic in all groups, with no abnormals noted in the control group. Key pinch was normal in all of the control group; however, was abnormal in the right hand in 15 of the V0-3 and SN0-3 groups, and the left hand in 15 of the V0-3 and 11 of the SN0-3 group. The largest number of abnormals appeared in the SN3 group. An increased number of abnormal pinch measurements were noted with the palmar pinch, two in each hand in the control group, 20 in the V0-3 and SN0-3 in the right hand, and 19 in V0-3 and 21 in the SN0-3 in the left hand. The largest number of abnormals were in the SN3 group. These findings were unexpected, as grip weakness is regularly reported to be common in the HAVS literature.

Two-point discrimination was abnormal in only one of the control group and in both hands, whereas it was

Table 3.—Physical Examination Results

	C	V0	V1	V2	V3	SN0	SN1	SN2	SN3
Cold digits plus erythema	1	0	0	0	0	0	0	0	0
Clubbing only	0	1	0	0	0	1	0	0	0
Erythema terminal digits	0	11	1	8	3	4	7	3	9
Erythema plus clubbing	0	1	0	1	0	0	1	1	2
Erythema plus thickened dermis	0	0	0	2	1	0	1	0	2
Increased palm sweating	0	0	1	0	0	0	0	0	1
Erythema plus clubbing plus thickened dermis	0	0	0	2	0	0	0	0	0
Erythema plus palm sweating	0	2	0	0	0	0	1	0	1

C=Control

abnormal in seven of the V0-3 and SN0-3 in the right hand and three of both V0-3 and SN0-3 in the left hand. Again the highest number of abnormals was in the SN3 classification.

Taking the 2.83 monofilament as being the normal testing level of sensitivity, and 3.61 as representing diminished light touch (Table 4) six controls were abnormal for right third and fifth digits, six for left third, and four for left fifth digit. None of the V0-3 or SN0-3 reported sensation at 2.83 for the right third digit, three did for the right fifth digit of the V0-3, and two SN0-3 group. All the remaining members noted beginning sensation at 3.61 monofilament level, 3.61 representing the largest number of all groups, less at 4.31, and only one noted sensation only with the 6.65 monofilament. Larger numbers of monofilament sensation responders appeared to occur in the SN3 group for all digits. Considering the 3.61 monofilament level as a borderline finding, the 4.31 appeared to have the largest number of responders.

Diagnostic Classification and Vibrometry Results.— The more discriminatory tests were compared against vibrometry results and final diagnosis in Table 5. As with previous descriptions, the largest number of physical examination abnormalities was that of erytheme of the terminal digits, with only four of the diagnostic group and none of the abnormal vibrometry group being normal. A total of 14 of the diagnostic group presented abnormalities, 18 of the V1 group, and two of the V2 group. Ten of the diagnostic V0 group were abnormal, and 17 of the SN2 diagnostic group. Of those with abnormal vibrometry results, eight had erythema of the terminal digits, with a total of 12 showing abnormal findings.

As with previously discussed results, abnormal dexterity was noted in the greatest numbers in the left extremity, and grip strength results were most abnormal in the palmer pinch in both hands. Vibrometry abnormals showed a higher degree of abnormal tests for two-point discrimination of the left hand and for palmar pinch grip in both hands. In general, abnormal clinical tests showed a higher percentage of abnormals when compared to clinical diagnosis than to abnormal vibrometry results.

Utilization of diagnostic classification and vibrometry results provided similar results for monofilament testing (Table 5) as described for comparison of such testing with Stockholm classification. The 4.31 monofilament remained the most sensitive, and again the largest number were in the borderline 3.61 group. Only a few noted threshold sensitivity with only 4.56 and 6.65 monofilament testing,

Table 4.—Monofilament Testing

	C	V0	V1	V2	V3	SN0	SN1	SN2	SN3
Right Hand									
Third 2.83	4	0	0	0	0	0	0	0	0
3.61	5	9	4	5	0	3	5	3	6
4.31	0	5	2	7	2	2	5	2	8
4.S6	1	2	0	1	0	0	0	0	3
6.65	0	0	0	0	1	1	0	0	0
Fifth 2.83	4	2	1	0	0	1	1	0	0
3.61	5	6	3	6	1	3	S	2	7
4.31	0	6	2	8	1	2	5	3	7
4.56	1	1	0	0	1	0	0	0	2
6.65	0	0	0	0	0	0	0	0	0
Left Hand									
Third 2.83	4	3	0	0	0	0	0	0	2
3.61	4	10	2	4	1	5	4	4	5
4.31	2	2	2	8	2	1	3	1	9
4.56	0	2	0	1	0	1	1	0	1
6.65	0	0	0	0	1	0	0	0	1
Fifth 2.83	6	2	0	0	0	0	1	0	0
3.61	3	10	4	7	1	4	3	3	10
4.31	1	2	2	7	1	2	5	2	6
4.56	0	0	0	0	1	0	1	0	0
6.65	0	0	0	0	1	0	0	0	1

C=Control

and none with abnormal vibrometry perceived sensation with the normal 2.63 monofilament. This implies that staging is the final standard, and may represent only symptom/test correspondence.

Actual vibrometry testing results (Table 6) revealed that of the control group three were abnormal at levels up to 250 Hz, six abnormal at 500 Hz, and one was normal at all Hz levels. One control was abnormal at 32 Hz, one at 125 Hz, one at 250 Hz, and six at 500 Hz. Of the exposed group, four were abnormal at 12 Hz, 13 at 32 Hz, one at 62 Hz, two at 125 Hz, five at 250 Hz, and 13 at 500 Hz. If one grouped all abnormals up to 250 Hz, 19 were noted in Stockholm classification V0-3, and similarly 19 were noted in addition at 500 Hz in both groups.

Table 7 compares the number of abnormal clinical tests to the control group and to the Stockholm classification of the group, taking the highest of either vascular or sensorineural for the rating of Class 1 through 3. The six tests utilized in this rating were dexterity, gross grip strength, pinch grip, monofilament testing, two-point discrimination, and vibrometry.

Of the control group, four were normal for all tests, one had one abnormality for 1, 3, and 4 tests, and three had two abnormal tests. Of the asymptomatic exposed group, two had one abnormal test, and one each 2 and 4 abnormal tests. Of the 1 group, four had one abnormal test, one had two, two had three, and one had six abnormal tests. Of the 2 group, two had one abnormal test, five had three abnormal, and one each 2 and 4 abnormal tests. Of the 3 group, five had one abnormal test, six had three, two had two and four, one had five, and one had six abnormal tests. Of those with three or more of these six clinical tests as abnormal, 2/10 or 25% were in the control group, 1/4 or 25% in the 0 group, 3/8 or 38% in the 1 group, 6/8 or 75% in the 2 group, and 10/18 or 56% in the 3 group.

Discussion

The objective and subjective components of hand-arm-vibration syndrome can lead to difficulties in diagnosis and in the staging of the syndrome in individual workers. The sensitivity and specificity of a test and it's positive and negative predictive values are particularly important issues when one selects a particular test modality.

In searching for a test modality, or modalities, one wishes for such a test to be highly sensitive as well as specific, and to possess strong negative and positive predictive values. In this shipyard study, we were screening for a test, or tests, to meet these qualities. Most previous literature dealing with this syndrome have failed to address these issues of sensitivity and specificity and their predictive values.[4,6-9]

In this clinical report, we have opted for utilizing the control group as that group without the disorder, and utilized three ways of looking at those with the disorder;

Table 5.—Physical Examination and Clinical Test Results *vs* Diagnostic Categories

	C	V0	V1	V2	SN0	SN1	SN2	VIBRO
Cold digits plus erythema	1	0	0	0	0	0	0	0
Clubbing	0	1	0	0	1	0	0	0
Erythema terminal digits	0	11	11	1	4	14	5	8
Erythema plus clubbing	0	1	0	1	1	1	0	0
Erythema plus thickened dermis	0	0	3	0	0	2	1	2
Increased palm sweating	0	0	1	0	1	0	0	0
Erythema plus clubbing plus thickened dermis	0	0	2	0	1	0	1	1
Erythema plus palm sweating	0	1	1	0	2	0	0	1
Abnormal dexterity right	3	1	3	0	2	1	1	0
Abnormal dexterity left	3	5	11	0	3	11	2	0
Two-point discrimination right	1	2	5	0	1	5	1	3
Two-point discrimination left	1	1	1	1	0	2	1	7
Grip right	0	3	2	2	2	4	1	2
Grip left	0	0	2	1	0	2	1	1
Tip right	0	0	3	1	0	2	2	3
Tip left	0	2	2	2	1	3	2	2
Key right	0	S	5	5	3	9	3	6
Key left	0	3	7	1	2	6	3	5
Palmar left	2	6	12	1	2	14	3	8
Palmar right	2	6	12	2	6	11	3	9

Control=Control Vibro=Vibrometry

the Stockholm classification of vascular and sensorineural groups 0-3, Dr. Cherniack's clinical diagnosis utilizing plethysmography, single frequence vibrometry, two-point discrimination, and monofilament testing, and vibrometry testing alone. Sensorineural and vascular Class 0 would appear to be a borderline group, either without disease or with disease but as yet not at a symptomatic stage.

The study of shipyard workers described by Cherniack et al dealt with a self-selected population of shipyard workers who were studied in a private occupational medicine clinic.[10] This group may be at variance with our reported series in several ways; most probably all were workers who were either referred for testing because of medical complaints, or were either self-referred, or referred by a union or an attorney. Also, in most cases, either workers compensation or an attempt to secure a work assignment change were at issue. By comparison, the group covered in this report were all actually working in their assignment as grinders, were not in any way seeking medical diagnosis or care, were not in the process of filing for worker's compensation, nor seeking assignment change. They were inclined to downgrade their disorder severity in order to remain at work in their present capacity. For these reasons, comparison of the findings in the Cherniack group, 98% complained of extremity numbness and tingling, 88% vasospasm, 62% of sensorineural symptoms of object control, and 61% of difficulty with coordination. In comparison, in our group, 36% presented with no vascular symptoms and 13% with no sensorineural symptoms. In regard to the Stockholm classification, 42% of the Cherniack group were Stage 1 sensorineural, 42% Stage 2, 14% Stage 3, and 2% Stage 0. Our group ranged as 26% Stage 1, 13% Stage 2, 48% Stage 3 and 13% Stage 0.

Of the Cherniack's group 25% presented with light touch abnormality, and 33% with two-point discrimination abnormality. Vibrotactic detection threshold was significantly higher in the more symptomatic group than the less symptomatic, as was a higher percentage with abnormal grip strengths; in their reported group, abnormal grip strength and increased vibrotactile threshold at 120 Hz were the most distinctive and prevalent findings, and were the most deviant quantitative measurements. The Cherniack et al paper also pointed out the inconsistency of association between objective test results and clinical staging, an observation also made by Gemme et al in 1987.[12] Cherniack noted the absence of an unexposed group in their study group, which they felt required a cautionary approach to inferences regarding prevalence of the reported abnormalities in a more controlled group.

Table 6.—Vibrometry Testing

Abnormal Results									
	C	V0	V1	V2	V3	SN0	SN1	SN2	SN3
16 Hz	0	1	1	1	1	0	0	2	2
32 Hz	1	4	3	4	2	1	4	1	7
62 Hz	0	1	0	0	0	1	0	0	0
125 Hz	1	1	0	1	0	1	0	0	1
250 Hz	1	1	0	3	1	0	2	1	2
500 Hz	6	6	3	3	1	2	4	2	5
Normal	1	0	0	0	0	0	0	0	0
Abnormal in Excess of 118 at 16-250 Hz									
Abnormal up to 250 Hz	3	6	2	8	3	2	4	3	10
Abnormal 500 Hz	6	8	4	5	2	3	5	2	9
Normal	1	1	0	0	0	0	1	0	0

C=Control

Table 7.—Number of Abnormal Tests

	0	1	2	3	4	5	6
Control	4	1	3	1	1	0	0
V/SN0	0	2	1	0	1	0	0
V/SN 1	0	4	1	2	0	0	1
V/SN2	0	2	1	5	1	0	0
V/SN3	0	5	2	6	2	1	1

They further pointed out the disadvantage of interpretation of clinical and psychophysiological tests that have a voluntary component. They felt, however, that such tests as two-point discrimination and vibrometry at 120 Hz threshold did tend to discriminate between symptom groups, and should be considered as candidates for studies in less-severely affected populations, since they were simple and quantifiable, and could be administered to a specific site of injury. Grip strength abnormalities were present in a higher percentage of the Cherniak group than in this report: 43% had abnormal gross grip strength, 33% key pinch, 22% tip punch, and 35% palmar pinch. The results in our study were 14%, 31%, 13%, and 41%, this reported series showing a significantly decreased number with abnormal gross grip strengths.

High frequency vibration, 80-400 Hz, which is detected by the Pacinian corpuscles, is a stimulus mediated in peripheral nerves by the large afferent myelinated fibers[14] and this vibration sensitivity is an indirect reflection of the functional integrity of the large afferent nerve fibers.[15] Rosencrance et al pointed out that the most sensitive frequency range in the evaluation of psychophysiological vibrotactile perception was between 250 and 350 Hz.[16] From their study, they postulated that the benefits of vibration sensitivity testing in industry may include early detection of peripheral neuropathy and periodic screening of workers at high risk might be a cost-effective approach to reduce its incidence. Such a possibility is partially demonstrated in this study, but due to its lack of sensitivity and specificity does not appear to be the answer when used as a single test modality.

Grip strength measurements were also noted to be of value in evaluation of more severe cases in the study of Bilge and Palmear.[17] They attempted to utilize this measurement in evaluating disability, but noted that the measure was not a functional test and not of optimal value in evaluating impairment. Results of our study would tend to underline this conclusion, especially when measuring only gross grip strength, but similarly this would pertain to the pinch indices. They also pointed out that for compensation purposes impairment must be rated, that the Stockholm classification does not translate to impairment, and an impairment classification must be accomplished by using the AMA Guides to the Evaluation of Permanent Impairment. Unfortunately, as of this time, hand-arm-vibration syndrome does not fit well into these guidelines. Aatola et al[18] have noted that the repeatability of vibratory thresholds (VPT) of fingers is good, and that VPTs of subjects without vibration exposure were most sensitive at 125 Hz. This finding was at some variance with our study, where the change appeared to occur between 16 and 32 Hz. Aatola et al recommended that VPTs should be used as a specific diagnostic test for vibration syndrome at the individual worker level, a recommendation that appears to be supported by this study. Interestingly, the Aatola group performed serial VPTs, and noted that the VPT of forest workers decreased only slightly from 1979 to 1983, suggesting that the mechanism of perception changes slowly, regardless of whether VPTs are improving or worsening, which would suggest the worthiness of serial testing of exposed workers.

Palmear and Taylor in 1991 noted that whereas initially it was thought that a single test would be sufficient to establish the diagnosis of HAVS, multiple tests were required to confirm and grade the severity of the vascular and neurological symptoms. They recommended the following regimen:[19]

1. Complete history
2. Complete physical examination
3. Specific tests, such as Allen's, Adson's, Tinel, Phalen, dynamometer testing, depth sense, and two-point discrimination
4. Laboratory investigations
5. Special investigations when indicated, such as plethysmography, finger systolic pressures, cold water immersion, nerve conduction, vibrometry, current perception threshold measurement at three sensorineural frequencies, as well as audiometry.

Since our study was in a shipyard medical department, it included their recommendations with the exception of the special investigations other than vibrometry (plethysmography was included in Martin Cherniack clinical diagnosis of the group), and the laboratory investigations, which did not appear to be indicated. The results of our study strongly support the conclusion that multiple tests are required for a proper diagnostic evaluation, and no single test is sufficient to establish the diagnosis of or severity of disease in this complex clinical entity of, as yet, not completely understood pathophysiology. As is noted in Lundborg et al[20] there are several types of mechanoreceptors that seem to respond to vibration which makes the physiology of tactile sensation so complex. Different categories of receptors have been defined on the basis of their adaptation to stimuli as well as on their receptive field properties. Fast adapting receptors respond only to skin deformation, while more slowly adapting receptors respond to moving stimuli and constant deformation. Fast adapting receptors consist of Meissner's and Pacini's corpuscles and Golgi-Mazzone corpuscles; slow adapting receptor to Merkel's cell neurite complexes and spindle shaped Ruffine nerve endings. The various corpuscles respond to different vibration frequencies, making the issue more complex, and thus point to the need to measure vibration sensitivity at a series of frequencies, the need for such being noted in this study. The work of Johnson and Phillips in 1981[21] regarding a spatial neural mechanism underlying tactile sensation further complicates this issue, and points to the problems inherent in monofilament and two-point discrimination testing, and suggest that gap detection, grating resolution, and letter recognition might be more discriminating, testing which we considered for this group but which was not accomplished because of the complexity of the test protocol.

Conclusion

Review of the results of the battery of tests performed in this group of shipyard workers indicated, as in other reported studies, the lack of sensitivity and specificity of any one test, including vibrometry. The general physical examination of the hands was the only modality which was uniformly abnormal in all workers exposed to vibration, and normal in all control subjects, with the exception of one. However, even this examination failed to distinguish between the symptomatic and asymptomatic workers. This could be either because the physiologic disturbance was not present in such workers at a symptomatic level, or because the examination was of a low predictive level and lacked specificity.

Examination of the mobility of the extremities and the various vascular maneuvers appeared to add little to the diagnostic regimen.

Of the other clinical tests, again it is noted that no one single test modality provided significant sensitivity, specificity, or predictive value. In comparison with other studies, the gross grip measurement was of little value in this group of workers, the pinch measurements, especially palmer pinch, being more sensitive and predictive.

The presence of positive Tinel, Phalen, and Finkelstein tests in the small number of examined workers suggests, as has been previously noted, the mixed nature of this cumulative trauma disorder, the largest number being noted in the sensorineural 3 group (SN3)

The dexterity testing, two-point discrimination, and monofilament testing do provide valuable diagnostic information,but not when taken as a single modality. This is representative of their lack of specificity and sensitivity as single test modalities. However, their strength as predictive test modalities is increased when they are taken as a group, ie, when utilized in addition to the physical examination of the hands, vibrometry, gross and pinch grip measurement, and Stockholm classification of symptoms. Unfortunately, vibrometry by itself without the multitude of testing modalities did not prove to be the predictive test needed to identify those workers in the shipyard with HAVS.

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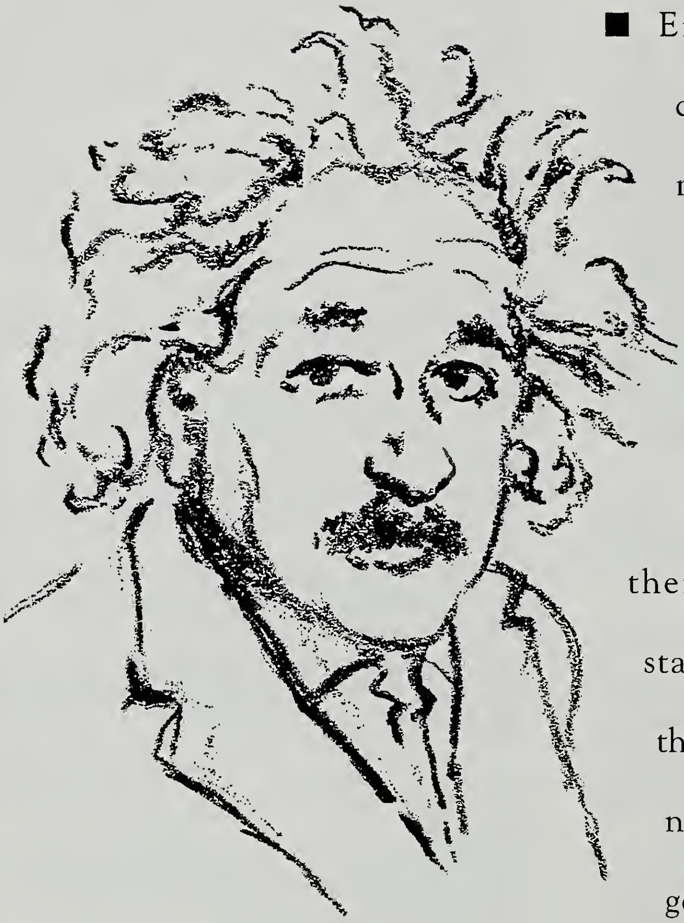

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Remifentanil (Ultiva™)

LAURA MILCH-WHITE, PHARM.D.

REMIFENTANIL is a new μ-opioid receptor agonist which is indicated for IV administration as an analgesic agent for use during the induction and maintenance of general anesthesia for inpatient and outpatient procedures. it is also indicated for continuation as an analgesic into the immediate postoperative period (under the direct supervision of an anesthesia practitioner in a postoperative care unit or intensive care setting), and as an analgesic component of monitored anesthesia care. Remifentanil has a rapid onset of action, short duration of action, and analgesic potency similar to fentanyl.

Mechanism of Action Pharmacology

Remifentanil is an esterase-metabolized μ-opioid receptor agonist. The molecule has a phenylpiperidine structure common to fentanyl and fentanyl derivatives, but also has a propanoic acid-methyl ester group that renders it susceptible to esterase metabolism. (Fig. 1) Remifentanil has a pKa less than physiologic pH, and circulates throughout the central nervous system in its uncharged lipophilic form.[1] The μ-opioid activity of remifentanil is responsible for its analgesic and anesthetic effects and is antagonized by naloxone. Affinity of remifentanil to δ and κ receptors is much weaker than for μ receptors.[2]

Remifentanil is contraindicated for epidural or intrathecal administration, due to the presence of glycine in the formulation, and is also contraindicated in patients with a hypersensitivity to fentanyl or fentanyl analogs. In addition, it has been found to cross and be metabolized by the placenta, and it is excreted in the milk of lactating rats.[3]

Pharmacokinetics

Remifentanil has a rapid onset and offset of action, achievement of peak effect, and response to titration. It exhibits dose-independent distribution into blood, rapidly perfused tissues, and peripheral tissues, as represented by a volume of distribution of 20-40 L. The duration of action (context-sensitive half-life) is three to six minutes and all effects should subside within five to 10 minutes after the end of infusion.[3,4]

The propanoic acid-methyl ester portion of remifentanil undergoes esterase metabolism by nonspecific esterases in blood and other tissues. The metabolism is unaffected by age, gender, weight, hepatic or renal function, or underlying disease state. The majority of the compound is metabolized to the primary metabolite of ester hydrolysis (GR90291), which is renally excreted and dialyzable. The other metabolite of remifentanil (GR94219) has not been detected in human blood. Because remifentanil is not a substrate for pseudocholinesterase, patients with pseudocholinesterase deficiencies are not at risk for a prolonged effect.[4]

Remifentanil has a terminal half-life of 10-20 minutes, effective biologic half life of three to 10 minutes, and is rapidly cleared at a rate of 2.5–3.8 L/min, regardless of dose, duration of infusion, patient gender, age, weight, renal, or hepatic function. The metabolite has been shown to have very low potency (1/4600 of parent drug) and may accumulate in patients with impaired renal function, but clinical effects of the metabolite have not been observed.[3,4]

Clinical Trials

In a multicenter evaluation of anesthesia for elective inpatient surgery, two different doses of remifentanil in combination with midazolam, propofol, and vecuronium were compared. Recovery from anesthesia occurred within three to seven minutes in both groups and there were no statistical differences between the measured parameters. Hypotension occurred most often during anesthesia induction, while bradycardia occurred most during maintenance. It was found that when combined with propofol, remifentanil controlled the responses to tracheal intubation and intraoperative response post-intubation and allowed for rapid recovery from anesthesia.[5]

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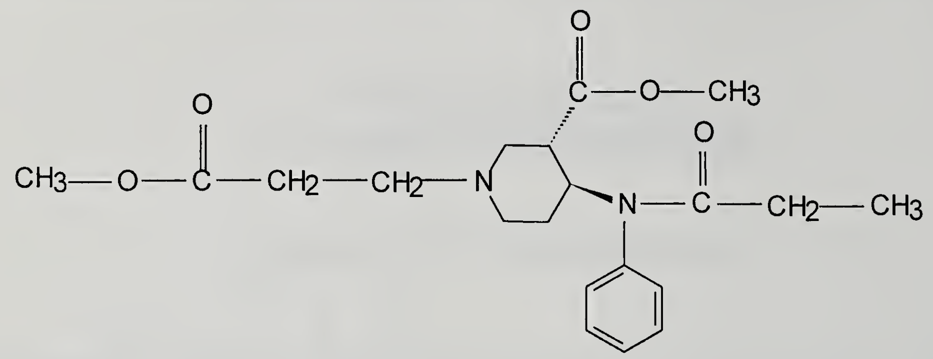

Figure 1. Structure of remifentanil

A number of studies and abstracts on remifentanil for use in general anesthesia and postoperative analgesia have been published and reviewed in the literature.[6] In a supplemental abstract for a comparative trial, remifentanil 0.25 mcg/kg/min resulted in better intraoperative hemodynamic control than alfentanil 0.5 mcg/kg/min in patients undergoing total abdominal hysterectomy.[7] In addition, remifentanil administration resulted in fewer patients requiring naloxone (25 *vs* 60%) and quicker recovery time (four minutes *vs* 10.5 minutes) relative to alfentanil administration[7], as well as rapid recovery after prolonged surgery.[8] Earlier discharge from the postanesthesia care unit with remifentanil than alfentanil was reported in another abstract (159 *vs* 190 minutes)[9] although other factors may be responsible for discharge delays.[10,11] Several sources have shown that remifentanil was better than similar agents (alfentanil, fentanyl) in controlling or preventing intraoperative stress and effectively achieving hemodynamic stability.[6-7,9,12-15] Postoperatively, patients receiving remifentanil required earlier analgesia than with alfentanil.[9] Other abstracts describing comparative trials between remifentanil and propofol demonstrated that remifentanil may be used as an alternative agent which may result in decreased pain associated with regional block placement, greater patient comfort, less sedation, decreased respiratory rate, and increased nausea and anxiety.[16-19] In one of these abstracts, faster recovery was associated with propofol.[19] Finally, in postoperative analgesia, remifentanil may be better than morphine at controlling pain, although again it was associated with decreased respiratory rate.[3,20]

Adverse Drug Reactions

Adverse drug reactions of remifentanil are dose dependent. Respiratory depression has been associated with infusion rates greater than 0.2 mcg/kg/min and bolus dosing postoperatively. Muscle rigidity may also occur with postoperative bolus doses. Rapid upward titration has resulted in apnea, respiratory depression, hypoxia, and muscle rigidity. Other potential side effects include bradycardia, hypercarbia, hypoxemia, shivering, nausea, and vomiting. Histamine release has not been observed with this medication.[1]

Administration and Dosage

Prior to administration, remifentanil should be reconstituted and diluted in a single syringe to concentrations of 25, 50, or 250 mcg/mL. Administration with blood should not occur in the same tubing, and all tubing should be cleared after final remifentanil administration.[3] Dosing in obese patients should be based on ideal body weight.[21]

General anesthesia—Remifentanil is not recommended as the sole agent for general anesthesia. For general anesthesia, remifentanil should be administered by continuous infusion at a dose of 0.5-1 mcg/kg/min through intubation. An initial dose of 1 mcg/kg may be given over 30–60 seconds if intubation is to occur less than eight minutes after the start of the infusion. Supplemental bolus doses of 1 mcg/kg may be given every two to five minutes to augment anesthesia during light anesthesia or transient episodes of intense stress. Bolus doses should not be given to spontaneously breathing patients. In patients suspected to have increased sensitivity to opioids (eg, elderly), the initial dose should be reduced by 50%.[3]

Postoperative analgesia—In using remifentanil as a postoperative analgesic, the initial rate of infusion should be 0.1 mcg/kg/min and should be adjusted every five minutes in increments of 0.025 mcg/kg/min to balance analgesia and respiratory rate.[3]

Monitored anesthesia care—As single therapy, 1 mcg/kg of remifentanil should be initiated 90 seconds before block placement and given IV over 30-60 seconds. If given in conjunction with midazolam, the dose should be reduced to 0.5 mcg/kg. As the sole agent, remifentanil should be administered by continuous infusion at a dose of 0.1 mcg/kg/min, beginning five minutes prior to placement of the local or regional anesthetic block. After block placement, the dose should be reduced to 0.05 mcg/kg/min and titrated in increments of 0.25 mcg/kg/min at five minute intervals to avoid hypoventilation. In combination with midazolam, the remifentanil dose should be reduced by 50%. It is recommended that supplemental oxygen be given to all patients receiving remifentanil during monitored anesthesia care.[3]

Cost

Ultiva™ average wholesale price (AWP)	
1 mg/3 mL vial	$ 9.75
2 mg/5 mL vial	$19.00
5 mg/10 mL vial	$45.00

Place in Therapy

Variations in study designs have not provided conclusive information in regard to the most cost-effective use of remifentanil. Study results may vary greatly depending on doses of remifentanil and comparative agents, time of administration of analgesics, and adjunctive agents used. It is clear that remifentanil has a pharmacokinetic profile that differs from those of similar agents, including alfentanil, fentanyl, propofol, and morphine. Remifentanil may have a role in short, painful interventions in emergency settings, day surgery, endoscopic procedures, or in longer procedures where predictable recoveries are crucial.[22] Postoperative pain may be harder to control if the effects of remifentanil diminish prior to initiation of secondary analgesia. Further studies and practical experience will determine if remifentanil will provide clinical differences in time to extubation, improved pain control, decreased time for recovery, decreased time in the postanesthesia care unit, improved hemodynamic stability, and general tolerability.

Conclusion

Remifentanil is the only μ-opioid receptor agonist which has esterase metabolism. Subsequently it has a distinct pharmacokinetic profile with rapid onset and offset of action, easy titration, and lack of accumulation, which is independent of the duration of use. Its tolerability is similar to other agents including alfentanil and sufentanil, but because the narcotic effects dissipate quickly, rapid use of an analgesic is required. All of these characteristics require careful use, aggressive monitoring, and administration only in the presence of trained medical professionals with appropriate medical equipment when using remifentanil in general anesthesia, as an analgesic, or in monitored anesthesia care.[23]

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A Community Hospital's Ambulatory Addiction Medicine Program

MARK L. KRAUS, M.D., DOUGLAS ZIEDONIS, M.D., MICHAEL A. FEINBERG, M.D., SAMUEL R. SEGAL, M.A., LESLIE ISRAEL, D.O., AND MATTHEW C. KRAUS, M.P.H.

IN the current economic environment, health-care cost containment is a high priority. As a result, ambulatory programs are often preferred to inpatient programs when clinically appropriate. Although addiction treatment has been shown, in general, to provide significant health-care savings,[1] research on outpatient addiction medicine programs provide two additional advantages: these programs are often less expensive than residential care and they are more acceptable to patients, who are not forced to leave their jobs or families in order to receive treatment.[2,3] Outpatient programs take advantage of the opportunity to incorporate the patient's normal interactions with the outside world into the treatment protocol. Health-care providers must be able to deliver a clinically efficient, cost-effective, and patient-centered treatment strategy that addresses both the medical and behavioral components of addiction. A model addiction medicine program is one that offers a full continuum of outpatient care delivered by a multidisciplinary team of professional care givers. West Main Behavioral Health of Waterbury Hospital Addiction Services is such a program. This outpatient, community-based alcohol and drug treatment program provides a range of services, including ambulatory detoxification to partial hospital management. It also serves as a community training and research site affiliated with Yale University School of Medicine. This combination of research and training works to the patient's benefit; while strategies such as motivational enhancement therapy, relapse prevention, 12-step facilitation, and pharmacotherapy are combined to form a comprehensive technology for treating addiction. This service conducts ongoing data analysis to monitor and improve the effectiveness of its treatment. Physicians, nurses, and counselors all contribute to the multidisciplinary treatment team, blending their resources with the Department of Psychiatry at the Waterbury Hospital into a comprehensive treatment system. This paper describes the philosophy and practices of an interdisciplinary addiction medicine treatment group in a community hospital outpatient treatment setting.

An important feature of any addiction medicine program is the manner in which it prepares patients for their reintegration into society; the "real world" encounters encouraged through the ambulatory setting ultimately work to the patient's advantage. Patients have the opportunity to practice coping skills in real-life situations and then return to the program to discuss their experience and receive feedback. Patients who successfully maintain the standards of treatment, often to their own surprise, gain a growing confidence that their situation can be improved. They begin to realize that complete abstinence from mood-altering drugs, through a structured clinical program, is a realistic and achievable goal. Earlier program evaluations of the model have been favorable (Cator/New Standards Inc.*). Outcome studies of patients who were able to achieve and maintain a three-month period of abstinence while in the treatment program, and who supplement their treatment with active involvement in the 12-Step pro-

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*New Standards, Inc. is a treatment outcome registry located at 108 Montreal Avenue, Suite 300, St. Paul, Minn. 55116, (612) 690-1002, Fax (612) 690-1303.

grams appear to have an increased likelihood of maintaining abstinence over the following three years.[4]

The extended care model of treatment also encourages patients to build and strengthen a healthy peer support network. Regular contact with other individuals assists patients in reinforcing their commitment to recovery, strengthens their level of personal confidence, and increases their openness to both positive and cautionary feedback from respected peers. Patients who are involved and invested in structured treatment with familiar peers and counselors have improved outcomes. In a trustful and therapeutic milieu, patients are more readily predisposed to acknowledge and discuss an isolated or episodic use of their drug. By talking about such incidents in a nonjudgmental environment, patients can handle a lapse or relapse and thereby learn something useful from the experience rather than hold onto feelings of shame, guilt, and defeat. Reviewing the details of such an event with supportive others assists the patient to recognize personal high-risk factors and to plan ways to address similar situations and circumstances that might occur in the future.

West Main Behavioral Health Program Setting

Waterbury Hospital is a 475-bed, acute care general teaching hospital serving a population of approximately 250,000. It is a site for Yale University's primary care general internal medicine training program, and is the addiction medicine component of the Department of Psychiatry at Waterbury Hospital, and provides a comprehensive ambulatory chemical dependency program.

Program Philosophy

This program is guided by the philosophy that chemical dependency is a treatable, chronic, and potentially progressive illness affecting the individual and his significant other(s) in the physical, emotional, and social spheres. The treatment approach incorporates addiction medicine and addiction psychiatry and 12-Step recovery principles. One of the chief tenets of this philosophy is that chemical dependency can be arrested with appropriate treatment and involvement in a long-term recovery program that often includes self-help groups.

The program's treatment efforts focus on the biological, psychological, and social aspects of the disease, with an orientation towards assertive early intervention in the illness. This approach addresses the agent (chemical of abuse), the host (the patient), and the environment, including family and employer.

The appropriate level of treatment intervention (low intensity outpatient, intensive outpatient, partial hospitalization, hospitalization, etc.) is determined based on the American Society of Addiction Medicine (ASAM) patient placement criteria. Many patients are able to benefit from outpatient detoxification and ongoing rehabilitation services. In some cases, coexisting psychiatric disorders must be evaluated and treated using the appropriate combination of medications and psychosocial interventions. Whenever possible, the family of the patient is engaged in treatment to provide education, support, and family treatment. Patients are accepted regardless of ability to pay and we see many State Administered General Assistance (SAGA), Medicaid, and Medicare patients in addition to those with commercial insurance.

Program Staffing

The multidisciplinary treatment team is made up of the physicians (internists and psychiatrists), certified chemical dependency nurses,[5] and certified alcohol and drug abuse counselors. The physicians are fully trained in addiction medicine (ASAM-certified) or psychiatry (board-certified) and provide oversight with respect to diagnosis, treatment planning, and clinical services for all patients. The physician meets with the rest of the multidisciplinary treatment team to conduct daily rounds with the team for all patients in the acute treatment unit (detoxification) and treatment planning for other addiction services.

The benefits of this multidisciplinary outpatient treatment model are many, particularly for hospital-affiliated treatment facilities that are struggling to survive in the intensely competitive and rapidly changing health-care environment. By integrating the disciplines of psychiatry, internal medicine, nursing, and substance abuse counseling in a single outpatient setting, West Main Behavioral Health is able to make available to patients convenient, effective, and cost-effective treatment. The program is committed to continuous self-assessment. It is able to provide the objective behavioral data essential in responding to the fiscal interests of managed-care organizations, in addition to a partial-hospital rate which compares favorably with the two- to six-times greater cost of inpatient detoxification or residential treatment.

Program Flow

The most difficult and critical decision a patient makes is the decision to enter the treatment system. Once patients have presented themselves for treatment of an addiction problem, they immediately become engaged in a full continuum of care. Treatment services flow smoothly from acute initial detoxification through a series of structured programs of graduated intensity into an ongoing supportive model of outpatient monitoring and maintenance of treatment progress.[6-8]

All of these treatment services and experiences are related to the patient's daily living environment. Ideally patients are treated for six months, during which they are assisted in building a solid foundation and social support network necessary for recovery. During this time, patients are offered four-hour partial hospital or three-hour intensive outpatient modules of care and supervision that include a period of detoxification ranging from four to seven days; a variable length of stay, three to five-day-per-week day or evening program, supplemented, if indicated, by a period of one-day-per-week relapse prevention partial hospital sessions; and three or more months of weekly aftercare group therapy sessions. All levels of care are contingent upon meeting the ASAM Patient Placement Criteria[12] (ASAM, PPC-2, 1996) for admission, continued stay, and discharge. The aftercare groups are structured to meet the individualized needs of patients, eg, men's and women's groups, motivational groups, social skills building groups, dual diagnosis, etc.

Program Components

The initial component of treatment is a comprehensive evaluation within the partial hospital program. Patients are medically screened by a physician and a nurse/chemical dependency counselor. If patients are found to have an acute medical, surgical, or psychiatric illness that warrants inpatient treatment, they are referred to the emergency department or the psychiatric crisis service for admission. Once stabilized, these patients then return to the acute treatment and evaluation unit (ATEU) for further ambulatory detoxification and relapse prevention planning and disposition.

Acute Treatment and Evaluation Unit (ATEU) Module

The ATEU is the entry level program allowing patients access to other services. The ATEU Program is a seven-day per week program provided within a partial hospitalization setting. The primary services provided within this unit include comprehensive assessment, basic orientation to the treatment process, engagement, biopsychosocial evaluation relative to chemical dependence, and outpatient detoxification from chemicals of abuse. Although the length of stay varies according to patient need, the average is four consecutive days. Admission to, retention within, and discharge or transfer from ATEU are all performed in adherence to patient placement criteria established by the American Society of Addiction Medicine.[9]

The core ATEU staff includes the medical director, the associate medical director, and the four addiction nurse/counselors. The medical directors are internists and addiction medicine specialists certified by the American Society of Addiction Medicine, while the counseling staff, all registered nurses, are both certified chemical dependency nurses (The National Consortium of Chemical Dependency Nurses) and certified substance abuse counselors (The Connecticut Alcohol and Drug Abuse Counselor Certification Board, Inc.). Additional comprehensive psychological assessment and/or management are provided as needed by psychiatrists and psychologists. The core ATEU team members meet daily to discuss individual patient progress and treatment.

Biopsychosocial evaluation in the ATEU is comprehensive comprising of physical examination, diagnostic testing, and a psychosocial interview that includes a baseline psychiatric evaluation, and may include discussion with a significant other. Prior to completion of this evaluation, a clinical summary is developed based on all the findings of the biopsychosocial evaluation; the summary identifies specific patient needs which form the basis for the master treatment plan.

While patients are undergoing biopsychosocial evaluation and/or detoxification, they simultaneously enter a program that serves as support for early relapse prevention as well as an introduction to the basic concepts in the next phase of treatment. Modalities utilized include films, discussion groups, and entry-level modules that address topics such as medical complications, nutrition, relaxation and stress management, weekend and daily planning, and orientation to self-help groups.

Outpatient Detoxification

All addictions are treated on an outpatient basis. In order to be admitted to the ATEU, patients presenting for medical detoxification must meet ASAM PPC-2 criteria.

After a history and physical examination, laboratory tests, radiological examinations, and electrocardiogram, patients receive treatment as needed for their withdrawal signs and symptoms.

Patients who are alcoholic and found to have alcohol withdrawal syndrome are treated (when indicated) with benzodiazipines, thiamine, and multivitamins.[7,8] To minimize craving, Naltrexone is ordered if there are no contraindications.[10,11] Antabuse is ordered for those alcoholics with impulsive drinking patterns as a deterrent treatment.[10]

There are no requirements to use medications during detoxification from cocaine dependence; however, cocaine-dependent patients seeking help to abstain are medicated with ammantadine and/or parlodel and/or desipramine and/or benzodiazipines, with a goal of reducing craving in order to minimize relapse risk.[8,12]

Patients who are opiate dependent are detoxed using clonidine and benzodiazipine and naltrexone.[13-15]

Those patients who are opiate dependent (heroin or prescription opiate addiction), that are either self-referred or referred by a methadone maintenance program for "agonist" free treatment are detoxified with clonidine and naltrexone. Opiate addicts not able to remain abstinent on an ambulatory basis are referred to an inpatient or a methadone maintenance program.

Some patients may need detoxification from cocaine or alcohol while continuing to be maintained on methadone, a service provided in cooperation with our local methadone program.

Partial Hospital / Day / Evening Treatment Module

West Main Behavioral Health's Day / Evening Treatment Unit is an intensive partial hospital treatment program for individuals and family members. Individuals admitted to treatment have been determined appropriate for treatment in a partial hospital setting by the multidisciplinary clinical team following completion of the acute treatment and evaluation unit.

The goal of treatment is complete abstinence from all substances of abuse, and to develop a recovery plan that addresses related medical, psychological, family, legal, and employment issues. The treatment unit's success relies on enhancing the patient's motivation to change, and increasing the patient's knowledge of the addiction and recovery process specific to his or her own experience of dependence or abuse of substances. Furthermore, the patient develops coping skills to avoid or manage triggers to substance abuse; gains practical knowledge of relapse prevention techniques; begins to implement such techniques while in treatment; and initiates the construction of a support network for recovery through primary relationships and social/educational work environments.

The treatment plans address individual needs. Family members and significant others are expected to participate in certain treatment modules when their involvement and support are necessary. The program focuses on orienting the patient and family members or significant others to the philosophy, practice, and benefits of specialized community self-help support groups.

The Relapse Prevention Low-intensity Treatment Module

The Relapse Prevention Track has as its primary objective the maintenance of the habit-changing process begun in the early stages of recovery. Patients continue developing skills to prevent relapse. All participants are expected to complete an educational component intended to prevent relapses by providing means for anticipating relapses, and strategies for interrupting them. In addition, each patient will be assessed for strengths and weaknesses in coping skills, ability to sustain changes in her way of living, and capacity to control daily life events. Patients participating in the day or evening treatment program may be referred to the relapse prevention module for adjunctive treatment.

Addressing Coexisting Psychiatric Problems

High rates of coexisting psychiatric symptoms and disorders are often uncovered among individuals with a substance use disorder. Depression and anxiety are common. These patients have been given the label of "dual diagnosis," however, this represents a heterogeneous population. There are numerous combinations based on the specific type of psychiatric disorder(s), substance use disorder(s), severity of symptoms, and motivation to address either problem.

Patients often require a comprehensive assessment of these symptoms to determine if psychiatric medications (which do not cause physical dependence) or psychosocial treatments (especially cognitive, behavioral, and family therapies) are required. In many cases with maintained abstinence the psychiatric symptoms resolve; these symptoms were most likely induced by the substance (either intoxication, chronic use, or withdrawal state).

Treatment of individuals with coexisting psychiatric and substance use disorders require an integrated treatment blending traditional psychiatric with substance abuse treatment. Education for the patient and the family is important. Psychotropic medications may be necessary for some. Each illness requires treatment to stabilize acute symptoms and begin the recovery process. Integrated treatment requires staff training and a unified conceptual and programmatic framework. Often patients with a chronic mental condition, have common features of chronicity, predictable symptomatology, and multiple relapses. Patients must develop behavioral strategies directed towards reducing and stabilizing both disorders. Integrated treatment is provided for patients who do not have a severe and chronic psychiatric condition (severe depression or psychosis, especially schizophrenia). These individuals receive specialized dual diagnosis treatment in the general psychiatry units. The emphasis of the dual diagnosis treatment program is on dual recovery and on helping the patient meet the treatment goals of abstinence and compliance with psychiatric treatments including prescribed medications. Patients who are unwilling or unable to participate in 12-step fellowships are offered a cognitive-behavioral treatment module and an introduction to a cognitive-behavioral therapy based self-help group.[7] This model has shown promise for the outpatient treatment of some dually diagnosed patients.[8]

Conclusion

In an era of health-care cost containment one must seek programs that deliver clinically efficient and cost-effective health care. A community hospital ambulatory addiction medicine program can provide: 1) cost-effective treatment that leads to future savings by increasing patient productivity in the community and decreasing their liability to legal, work, or health-care problems and the associated costs; 2) an educational environment that teaches future practitioners of primary care general internal medicine how to make efficient and effective evaluations and treatment for chemically dependent and dually diagnosed patients; and 3) a multidisciplinary treatment team approach that creates a successful therapeutic milieu for chemically dependent and dually diagnosed patients.

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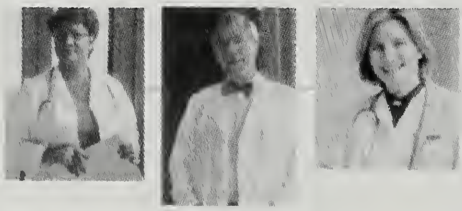

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Guest Editorial

Why Not to Invest in a Publicly Traded Managed Care Company

The big secret is out on managed care from the investor's point of view. Manage-care companies are a shining example of why investing in a company that neither makes a "widget" that improves the quality of life nor provides a service that enhances, magnifies, or makes speedier current technology is wise. Managed-care companies, no matter which one you look at, take precious health-care premium dollars and sift off the top to make what they call "profits," and expend large amounts of the remaining premium to cover a vastly increasing overhead while they try to "grow."

This "growth," costs a lot of money. It means buying new powerful computer systems, building or renovating new office space, and hiring everyone from financial analysts, to market share strategists, to nurses who agree by incentive to screen phone inquires with quotas for care denial. They really make money by having these highly trained businessmen figure out ways to not spend your premium dollar. The more successful they are at it, the better their balance sheets look, which means less premium dollar there is for paying for doctors, hospital, labs, and most ashamedly, medical research.

When state legislatures, backed by the real health professionals, your doctors, force HMOs to increase coverage for services, they try and usually succeed to extract the cost from the people battling for the consumer's or patient's rights, your providers. They know that physicians are barred from fighting collectively because of antitrust laws, and thus, another way they can remain profitable despite legislative action. This is morally unjust and since it can not last for fear of eventual provider revolt or nonparticipation the profit risk is in fact risky for an investor.

Since no real product is made, and no real service is rendered (the providers and facilities really do all the providing), then where is the appeal for the investor? What do these companies really sell other than a scheme to take money from their own investors' premiums, and devalue them by falsely making the investor think that he can really get the same quality of service from three dollars of care as be can from 10 dollars worth of care?

The ability to be profitable really depends on both skimming premium dollars off before services are paid for, and elaborate schemes to deny care or coerce providers to not provide the best care possible. These schemes called pretreatment authorization, and utilization review extend huge amounts of premium dollar in overhead to function, and further erode the value of the premium dollar.

Providers toe the line when they are forced to accept economic credentialling, or being labeled overutilizers. By forcing providers to be like insurance companies, they put the medical loss risk on the physician and hospitals. These entities then try to avoid being crushed by even worse revenue than their already steeply discounted fees cause. Economics 101 teaches us that businesses do not last long under these pressures.

When the providers refuse to participate, and institutions refuse to contract terms that are literally economic suicide, HMOs then will see their panels begin to shrink, and the value of the premium dollar further erode with quality providers not participating. It seems that if the only real product that the HMO industry can offer to sell is value for the premium dollar, then the way they actually devalue the very product they sell makes investing in them inadvisable.

Does an investor really want to take a risk on investing hard earned money on companies that profit from and cripple the very institutions and professionals that they hope will be there when they are ill and incapacitated? The Fairfield County Medical Association in Southwestern Connecticut recently completed a survey of its physicians that showed that neither physicians nor their patients felt that on a majority of important issues, not one of the surveyed HMOs excelled or even satisfied the majority of respondents needs. What kind of value is that?

A once profitable regional HMO's recent plunge in stock price points out that in fact their investors have figured out that they really do not have any hard product or "widget" of value to sell and have no service such as value for the premium dollar to offer. In fact, all of the major HMOs in Connecticut for 1998 have announced no more than modest premium increases, while still trying to force providers and hospitals to take less money for their services.

Since one major regional HMO just negotiated a settlement in New York for one million dollars in interest on outstanding payments to doctors and hospitals, (that they blamed on computer errors) it seems the interest HMO's make on the "float" is in fact one of the only remaining ways they can make a "profit" that does not entail either hurting those very providers the investors rely on to keep them healthy enough to invest at all, or raising premiums of their investors that takes money away from their ability to invest.

With actually no real device to sell or service to provide, and no real way to be profitable other than devaluing the actual health-care premium dollar of its own investors, HMOs really have nothing to entice investors their way. Now that doctors are learning to say "NO" to unacceptable fees, and hospitals are realizing that taking the insurance companies risk on board will send them into bankruptcy, the people that the HMOs rely on to herd, slaughter, and capitalize from are becoming unavailable to profit from. The only people left to profit from soon will be their own investors through large increases in their premiums.

F. Scott Gray M.D.
Diplomate of the American Board
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Danbury

"Slow Down, You Move Too Fast"

The *Wall Street Journal* reported last week that the share price of Oxford Health Plans had risen sharply on the basis of a rumor circulating "on the street" that Aetna/US Healthcare was interested in acquiring an interest in Oxford.

I must confess that the thought of further corporate consolidation in the managed-care environment of Connecticut is distressing to me because it moves us one step closer to a single payor system in which the payor is an investor owned, for-profit organization, interested more in improving its bottom line than in providing for the health-care needs of its members.

A reduction in the number of managed-care organizations in this state will have adverse effects on patient care. Physicians and hospitals would become increasingly powerless to advocate for patients, for the threat of being denied access to a large number of covered lives would certainly stifle open dissent between them and a monopolistic managed-care organization. In addition, a monopolistic managed-care organization would be less likely to offer innovative health-care options to their customers. The "major choice" offered to customers of the old AT&T was what color their telephone would be. On the other hand, the break up of AT&T and the creation of several independent business that competed on the basis of services offered and cost led to the development of cellular and digital technology.

The fear of creating an economic catastrophe in the health-care sector is also of great concern. Only this week, members of the New York State Medical Society were forced to sue Oxford Health Plans for nonpayment of claims. Imagine how an individual Connecticut practitioner would fare if a major managed-care organization which controlled the vast majority of that physician's accounts receivable were to delay payment as a result of fiscal mismanagement within the managed-care organization. It is likely that if physicians were denied access to payments owed them for a prolonged period of time, many of them could not meet their monthly office expenses and would be forced to close their practices, leaving large numbers of patients with no medical care. Likewise, the economic demise of a major managed- care organization with an extremely large number of covered lives could bankrupt many hospitals in the state who depend on the income provided by managed-care contracts. Most hospitals in this state operate with a financial reserve that translates into only a few days of operating expenses. Many of these institutions have been struggling as of late; a prolonged delay in contract payments to these institutions would rapidly deplete their reserves and lead to their inability to provide medical care within their communities.

The track record of managed-care companies is not comforting. Almost every managed-care organization currently operating within Connecticut has experienced economic difficulties at one time or another and several have been acquired by their competition when they were unable to amass appropriate fiscal reserves. However, acquisitions are not always an appropriate solution for financial insolvency because sooner or later one reaches the point at which either there is a true monopoly, in that only one company remains, or we discover that there are no organizations willing or able to acquire another. The result is the demise of a major player, the creation of a large number of uninsured persons, and economic hardship for all health-care providers. For those who view access to health care as an issue of individual rights, this creates an unacceptable situation. Organized medicine must react quickly to this impending threat to health-care delivery. We must alert the public and our legislature. Mergers and acquisitions of managed-care organizations must be carefully studied so that the sequelae of a failed venture is fully explored. Truly, we must "slow down" because we are "moving too fast."

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Associate Chief, Department of Medicine
and Associate Chief of Staff, Yale-New Haven Hospital;
President, New Haven County Medical Association;
Clinical Professor, Department of Internal Medicine,
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Commentary

The Corporatization of the United States Health-care System

We are in the midst of a momentous transformation of the United States health-care system. For most of this century medical care has been regarded as a social service, largely provided by not-for-profit, public or private hospitals and by private solo medical practitioners. For the past few decades most medical care has been paid by third-party insurers (public or private) through reimbursement of the bills submitted by the providers. This open-ended charge reimbursement system encouraged the first major corporate entry into the health-care system in the late 1960s, in the form of investor-owned chains of hospitals, nursing homes, and various types of ambulatory care facilities.

In the late 1970s and early 1980s public and private third-party payers began to revolt against the constant inflation of health-care costs. The federal government tried to slow the escalation of its costs by instituting DRG Medicare payments to hospitals and using a fee schedule for physician reimbursements, but this has been only partially successful and Medicare costs continue to rise rapidly. Large employers were more aggressive and began to negotiate prepaid contracts with managed-care plans that accepted the risk of controlling costs through HMOs, IPAs, and PPOs. Not-for-profit HMOs had been on the scene for decades but had managed to capture only a relatively small fraction of the market. Almost all of the numerous new managed-care insurance plans that began to appear in the 1980s were investor-owned for-profit corporations.

By the presidential election of 1992, health care had become a major public issue. Clinton's campaign promised control of rising costs and extension of coverage to everyone, and protection of health-care quality. But his elaborate national health reform plan, based on regulated competition among managed-care plans, was defeated in 1994, leaving a vacuum into which private managed-care businesses and an enormous variety of private for-profit health-care delivery organizations rapidly expanded. At present, the great majority of managed-care plans are investor-owned. So are most nursing homes, private psychiatric hospitals, and home health-care providers. Ambulatory care facilities, such as surgicenters, dialysis centers, diagnostic laboratories, and imaging centers, are almost all investor-owned. About 15% to 20% of all acute care hospitals are also investor-owned and, until very recently, not-for-profit hospitals were being rapidly taken over by investor-owned hospital companies (chiefly, Columbia/HCA).

At present, I would estimate that at least 40% of all monies paid to facilities that deliver personal health care and at least 80% of all payments to private health insurance are collected by investor-owned for-profit corporations. This huge market is highly profitable, as Wall Street investors know very well. The gross revenues of this market are hard to estimate, but I would guess that the profits and corporate management and overhead expenses in this market currently extract $75–$100 billion from the nation's commitment to health care. This is money that otherwise could be spent on health-care services in an efficient totally not-for-profit delivery system.

About $150 billion of the $800 billion now being spent on personal health services goes to physicians, whose professional and office expenses account for about half of that amount. Physicians have been feeling increasingly helpless as individuals when they are forced to deal with managed-care corporations, and they have lately begun to organize themselves into groups that can negotiate collectively with managed-care insurers. A few of these groups are physician-managed and even not-for-profit, but for the most part the physician revolt against managed care has been coopted by physician management corporations that are rapidly springing up all over the country. They buy practices or contract with physicians on a profit-sharing basis. They are in essence middlemen who extract their own share of profit from the health-care dollar by providing services to doctors and signing favorable contracts for their members.

This vast corporatization of medical care has not only created profitable new markets for investors and entrepreneurs, but has fundamentally altered the role of physicians in the delivery of health care. In many instances physicians are no longer acting as autonomous professionals, but rather as employees, contractors, or agents of corporations that are in effect practicing medicine. Conflicts of interest are everywhere, and the traditional trusting relationship between doctors and patients is being eroded. The recent astonishing revelations about Columbia/HCA, (the largest U.S. hospital and health-care corporation), and the growing popular backlash against managed-care plans are signs of the fundamental malaise in our health-care system.

This problem results from a clash of values: Health care as a social service provided by dedicated professionals and not-for-profit community-based institutions *vs* health care as a service industry dominated by considerations of profit and entrepreneurialism. This conflict will be played out over the next decade or so as we test the virtues, dangers, and limits of markets in health care.

Since, by its essential nature, health care can never be satisfactorily distributed by markets, I confidently predict the present state of affairs will not last. Some time, early in the next century, we will once again begin moving towards national health-care reform. For reform to become a reality, however, physicians will have to be more proactive and supportive than they were in 1992–94. Only they are licensed to practice medicine and therefore they will have to take more initiative in planning for reform.

The funding of health care will have to be put on a much sounder basis than the present, inequitable patchwork, and middle-men insurance companies and employers will have to be taken out of the loop. In my opinion, the best solution would be some kind of earmarked national health-care fund, in which all citizens would contribute according to their means, which would be administered by a new public/private agency. The delivery of health care will have to be more socially responsible and more affordable than the now moribund open-ended fee-for-service system whose bankruptcy opened the door to corporate medicine. To be acceptable in American society, however, any new delivery system will have to remain in the private sector and be locally controlled, but it should also be not-for-profit.

How to achieve these or other changes in the funding and delivery of health care will engage the attention of planners, pundits, and politicians for the next decade or so, but major reform, I believe, is inevitable.

Arnold S. Relman, M.D.
(Presentation at the Capital Area Health Consortium,
T. Stewart Hamilton, M.D. Conference, Farmington,
31 October 1997)

Memo to: Executive Directors and Deans
State and County Medical Societies
Group Practices
Medical Schools

From: Reed V. Tuckson, M.D.
Group Vice President Professional Standards

Date: January 28, 1998

Subject: Conference on Genetic Medicine and the Practicing Physician

Genetic medicine is the future and the future is now. Every practicing physician today needs to have knowledge of genetic medicine.

Your members are invited to join the nation's premier genetics specialists to examine the medical, ethical, and legal aspects of genetics medicine at a conference designed for today's practicing physician. This conference will help physicians deal with important issues such as when to recommend genetic testing, how to respond to patients' questions, how to respond to requests for medical records that contain genetic test results, and how to access up-to-date genetic information on the Internet.

The American Medical Association, in partnership with AAFP, AAP, American College of Medical Genetics, ACOG, ACP, American Society of Human Genetics, ASIM, CAP, and the National Human Genome Research Institute of NIH, is holding this national conference March 13–15 in New Orleans.

We would greatly appreciate your efforts to promote this conference to your members.

For more information, contact Conference Director Karen Goraleski at (312) 464-4840 or karen_goraleski@ama-assn.org

Or visit the AMA website at http://www.ama-assn.org/about/events/gmpp-98gentest.htm

50 Years Ago

From *The Connecticut State Medical Journal*

February 1948

Personality and Practice

> The treatment of a disease may be entirely impersonal; the care of a patient must be completely personal.
>
> Francis Peabody

MANY of the physicians who happen to be members of the Society of the Sigma Xi have doubtless read an anonymous article which appeared in the autumn issue of the Society's official journal, *American Scientist,* under the caption "Machine Age Medicine." The writer is obviously an intelligent individual with scientific training, an excellent command of the English language, and a clear though somewhat pungent style.

The main thesis of his article, to put it broadly, is that the increasing technical trend in medicine has resulted in the transformation of practice from a profession to a business, and in changing the specialists in various branches of medicine from sympathetic human beings to scientists in whose veins circulates not blood but ice-water. The opening sentence in his article gives a key to its tone: "The practice of medicine has become big business." He comments on the fact that in the cities "the old time family doctor has largely disappeared, and in his place are cold-blooded specialists, aloof and detached." He enumerates their characteristics in detail: lack of interest in symptoms, an assumption that the patient is, *ipso facto,* a dumb egg, remoteness, and, in general, the characteristics usually associated with pompous and opinionated stuffed shirts. But this is not the whole sad story for, according to this critic, the few general practitioners who remain in cities are Caspar Milquetoasts, lacking in both knowledge and self-confidence, who refer their patients to "Aesculapian Oracles" because, overwhelmed by the mass of new discoveries in medicine, they hesitate to treat them themselves. "They have become medical directories," he says, "whose function appears to be to recommend specialists. For this service they usually charge their normal office fee," which, considering that they presumably examine the patient before referring him, seems not unfair. The rest of the communication describes the proceedings of various types of specialists and recounts the transfer of the harassed patient from one variety to another and his final deposition in the lap of some unfortunate neuropsychiatrist, evidently of the Freudian School. All in all it is a piteous tale, calculated to bring tears to the eyes of even a pathologist, and the writer of this editorial would be the last to deny that it could happen. Indeed, one can well imagine that a performance such as this patient describes might easily result in a very natural reaction leading to this kind of indictment.

The trouble with the picture is that it is somewhat out of focus, and that the writer, who perhaps has been put through a medical "third degree," has drawn the conclusion that his experience is the usual one. He apparently does not know that there are plenty of figures to show that the common diseases are simple and easily handled by the general practitioner, and that patients referred to specialists usually present an obscure and perhaps complicated picture, although some, notably neurotics, are referred because they themselves demand it. It is rather curious that these charges should have appeared at the very time when the American Medical Association, the official representative of the Nation's largest body of physicians, is glorifying the General Practitioner and offering new ways of keeping him abreast of the advances in medicine. One wonders too, whether the critic is aware of the numerous staff meetings held by hospitals, of the educational activities of city, county, state, and national medical societies, of the clinical conferences staged by local and national associations, and of the flood of medical literature, much of which is available in one form or another to both general practitioners and specialists. It is true that neither attendance at medical meetings nor reading of medical literature is obligatory, and that much depends on the industry of the individual practitioner, and it is likewise true that no mind can compass the advances in the entire field of medicine. Nowadays the same situation holds in many other callings, though not always to the same degree, and must be overcome by publications which correlate and synthesize knowledge. In medicine there have been such journals for years.

Reprinted from the *Connecticut State Medical Journal*, February 1948.

As to the organization of the busy doctor's office, this is more formal, and indeed more businesslike, than it was a couple of generations ago. It is notorious that in the horse and buggy days many doctors were exceedingly lax in the conduct of the business side of their profession. I assume that the critic would agree that in order to practice medicine successfully it is necessary to have the funds to purchase food, shelter and the other accessories necessary to support and raise a family. Then perhaps he has overlooked the fact that there is an agency known as the Internal Revenue Department which demands accurate figures in connection with the declaration of an income tax and the allowable deductions. So that there are excellent reasons why sensible physicians have become more businesslike than they were forty or fifty years ago. However, it must be admitted that there are some physicians in whose eyes the almighty dollar looms larger than in those of others, in a word there are physicians who charge all that the traffic will bear as if the fact that they treat many patients free were an excuse for this, which it is not. But here again we are not dealing with the decent majority who despise such actions as well as condemning fee splitting, rebates from supply houses and the like.

But, when all this has been said, the fact remains that the most important criticism in the anonymous article is the accusation of a lack of humanity in the specialists of today, who, by the way, constitute about 50 per cent of the regular profession. Science, of course, must be impersonal, but medicine is not a science, being compounded of both science and art. It is hardly necessary to point out that all types of individuals go into medicine and not all from the same motives. We have our misfits, our shysters and our stuffed-shirts, just as do the Law and the Ministry, but they constitute a small minority, and there has never been a time when the mass of the profession failed to grasp the importance of satisfactory personal relations between physician and patient, indeed, as Peabody says, "the essence of practice is that it is an intensely personal matter." Confidence in the physician is at all times important, and it is hardly heresy to say that in some situations it is more important than modern methods of treatment. A patient is expecting too much, however, if he visits a strange consultant and expects of him the same familiarity and camaraderie that he would get from his old family doctor, but he is certainly entitled to a sympathetic hearing and kindly treatment; if he fails to get these he has probably had the bad luck to fall into the hands of a tactless and inconsiderate practitioner, though not necessarily an incompetent one. There is perhaps truth in the idea that some men who are immersed in the study of medical science lack sympathy and facility in handling patients, though this is by no means necessarily the case and is equally true of some general practitioners. As the French put it: "L'Amour de la medecine fait le savant, l'amour du malade fait le medecin," or in Francis Peabody's words: "the secret of the care of the patient is in caring for the patient."

G.B.

THE PRESIDENT'S PAGE

An Alternative from the Midwest

So you feel discouraged, maybe demoralized, by the socioeconomic forces buffeting your practice? Despite the exhortations of the State Medical Society, you feel unempowered and disenfranchised. Do not lose heart, head, and control of your practice. This page tells a story that provides an object lesson to us, just when we need it, that market forces can in fact be the physician's friend.

In Minneapolis, a large number of the region's largest employers have united to bypass that state's HMOs, contract directly with physicians, and form an organization called the Buyers Health Care Action Group. The physicians involved are free to charge, organize, and operate as they choose, but not with absolute impunity. Greedy, cavalier over-utilization by physicians should affect them negatively. Responsive service should be rewarded.

There is the question why these large corporations are taking internally the chore of managing their own health-care system. Part of the answer lies in the experience these employers have had with managed-care. Remember, this is one of the areas where managed care got its start some 30 years ago. This market has matured to the point that essentially 90% of the work force in the metropolitan area is enrolled in a managed-care health plan, a rate roughly three times the national average. It turns out that the U S. health-care system hijacked by the managed- care approach may very well be less responsive than the old much maligned fee-for-service system. Such dominance of market share essentially eliminated competition among the existing HMOs. Premiums were rising steadily. Virtually every physician had to join the dominant HMOs to survive, homogenizing medical care. There really were no incentives to reward outstanding performance or even efficient operation

As the HMOs became ever more dominant, the employers lost more and more negotiating leverage. New services were not being offered. Access to information systems became increasingly restricted. An incident involving an employer-sponsored HMO in competition with the big three convinced the employers that an innovative approach was mandated. The incident involved the streamlining of treatment for a particularly common condition proffered by a physician specialty group that resulted in more rapid cures and a resulting cost savings of some one quarter million dollars. The plan administrators, of course, absorbed the savings for themselves.

The conclusion reached inevitably by the Buyers Group was that no significant reforms to the existing system were possible until the physicians obtained far more control over the medicine and economics of their practices than currently existed. The result is a hybrid of the fee-for-service and capitation model. The physicians decide on a rate of charge for a variety of services of varying complexity. The employer group referencing the prior years' records for the particular patient group in question determines the payments to be allocated based on the physician's rate. Each quarter utilization is analyzed and cost projections and reimbursement patterns are adjusted. This approach deals with the conundrum of too many unexpectedly sick patients at a given time.

Another unappetizing consequence of managed care was also addressed by this approach. That of rewarding physician groups with a generally more healthy patient mix than the population at large. Plainly speaking, the temptation to attract healthy patients to the exclusion of sicker ones fostered by the capitation system and per member per month rates is remedied.

Let me emphasize that this is far from the old laissez faire approach to medical reimbursement. The cornerstone of the plan is a variation on a consumer report card. Not just the employer group but patients and other physicians will know the price of good service, too much service, or poor service. Still uncertain are the consequences of the new report card. The theory is that charging too high a price for a poor product will result in patient defections. The $500 personal family premium for selecting outlying physician groups is expected to be an additional motivator.

The results of this experiment are easier to quantify when applied to physician behavior than its effect on influencing patient behavior. A few patterns have emerged. For most people who do not use the health-care system very extensively, price sensitivity is very evident. Conversely, sicker patients tend to be reluctant to switch doctors and in some instances appear to gravitate to higher cost groups expecting more responsive service. There are physician groups that have increased their fees when expectation of increased patient volume were not realized.

So the jury is still out on the ultimate success of this initiative. It is probable though that our consumer patients will continue to demand more economic and quality-of-care information. Systems such as the one described empower both the physician and the actual payers and as such are worthy of our attention.

Stanley J. Keating, Jr., M.D.
President

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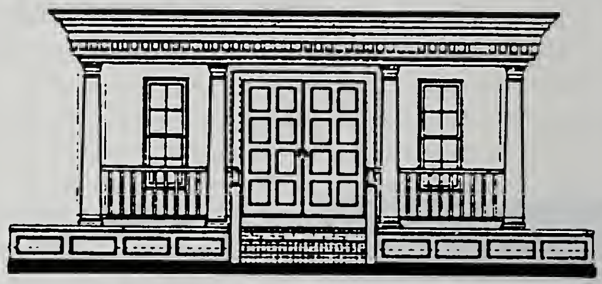

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What About Character?

ROBERT U. MASSEY, M.D.

> There never was a bad man that had ability for good service.—Edmund Burke

DURING our discussions of medical ethics, I often ask the small group of residents and fellows to consider the maxim that Hermann Nothnagel (1841–1905) offered to his students at the Vienna Medical School in his inaugural address in October 1882: "Only a good man can be a great physician." What I want them to think about is virtue ethics, once defined as what we do when no one is watching.

When, during ceremonial occasions, Nothnagel is invoked at the beginning of a lecture, few recall his maxim because it seems to be a truism, but in a small group someone may be brave enough to challenge it, and a lively discussion follows: "What do you mean by 'good'—whose good?" "Why does what you do in your private life have anything to do with your job, as long as you don't break the law?" "Isn't 'good' relative, depending on the situation, including the possible consequences? And isn't competence more important?"

This month the discussion moved quickly from doctors to lawyers to politicians to Bill Clinton. "If he's doing a reasonable job as president, what difference do his alleged sexual foibles have to do with it?" Then someone else mentions other presidents, usually Kennedy and Jefferson, maybe FDR. We never come to closure; if I were to tell them what I thought, pursue the issue to its conclusion, I would be dismissed as a hopeless remanent from the Victorian age, although in our ahistorical times few of them would have any clear idea when that was. By then I'm sorry that I spoke of the old Viennese professor, and move on to mentioning the classical virtues of prudence, courage, wisdom, and justice, and suggest that we try to figure out what those words mean and why they may be important in medicine and what other virtues they believe essential, such as honesty, temperence, empathy, practical skill, and integrity.

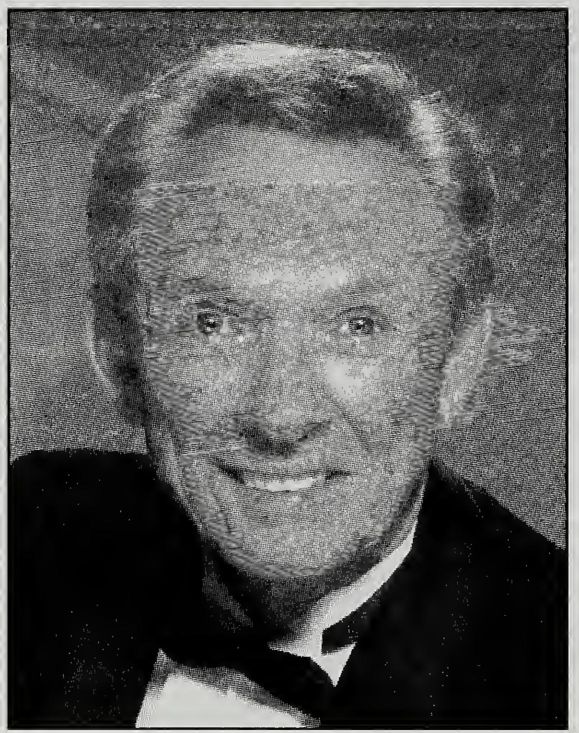
I remind them that ethics comes from the Greek *ethos*, habit, custom, manners, and that moral comes from the Latin *mos*, custom, and in the plural, *mores*, it means character. Both imply habitual behavior, suggesting that the ancients, and that includes almost everyone up until the 1950s, believed that good behavior defined character and that it must be acquired through steady habit, like any other skill. If someone lacked it, that lack had an effect on his behavior that was global. Liars lie, poor judgment repeats itself, philanderers philander, cheats cheat, thiefs steal, poor cabinet makers make drawers that stick. In a society where most of the citizens formed virtuous habits, few laws were needed. In a society in which getting caught is the thing to avoid, watch out for that tailgater; he may shoot you.

In her book, *The De-moralization of Society,* Gertrude Himmelfarb cites graphs showing that crime in England and Wales fell dramatically during the later Victorian period, 1860–1900, by about 50%; it did not rise again significantly until 1960, after which it increased almost 10 fold by 1991. In this country crime tripled between 1960 and 1980. Illegitimacy in the United States remained almost constant at about 2.4% of all births from 1920 until 1960 when it began to rise and reached about 30% of live births by 1990, a 13-fold increase, in spite of easy abortion, the pill, and intense sex education and sensitivity training by those who know all about it. Few could argue that our customs, character, and habits—our "values"—have not slipped significantly since the liberating '60s. Himmelfarb notes that "The present illegitimacy rate is not only unprecedented in the past two centuries; it is unprecedented, in American history going back to colonial times, and in English history from Tudor times."

There are signs that words like "lifestyle" and "values" may be going out of style, that tolerance of everything and anything, upheld as the greatest "value," may be questionable, and that what we do when no one is watching may, in fact, be somebody else's business. There is a creeping unease about postmodernity; our intellectual masters, who by now have tenure, counsel us to wait, assuring us that we'll get used to it all, that disorder is the price of freedom, whatever. Increasingly though we hear more about virtues, less about systems of ethics, less about rights, more about duties; Himmelfarb points out that even the First Lady supports a "Politics of Virtue." Perhaps the tide is turning.

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

Stuttering Didn't Silence His Song.



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This Month's Reading in Review

TIMOTHY B. NORBECK

"Why is it that doctors and nurses are accountable for their health-care treatment decisions and managed-care companies are not?"

> Texas state Senator David Sibley (R), sponsor of the Texas legislation allowing patients to sue managed-care plans.
> *The Wall Street Journal* (12 January 1998)

"Health plans can't have it both ways. They can't take the position that they save money through effective utilization review, and then, when something goes wrong, say, 'It has nothing to do with us.'"

> Robert Berenson, from the Lewin Consulting Group, agreeing with Senator Sibley.
> *The Wall Street Journal* (12 January 1998)

"Declaring that national legislation is needed to combat HMO abuses," U.S. Senator Barbara Boxer (D–Calif.) "proposed a bill of rights for health care consumers." She went on to say at a San Francisco news conference, "The only way to make certain that every insurance plan is held accountable for quality is to pass a national law."

> *San Francisco Chronicle* (7 January 1998)

The State of Florida was to receive $11.3 billion in the settlement of its case against the tobacco companies.... The only catch was that its lawyers were claiming as much as $2.8 billion in legal fees.... But Circuit Court Judge Harold Jeffrey Cohen ruled against them, pointing out that the fee they were claiming mounted to $7,716 an hour for each of the attorneys and would have required them to work 24 hours a day for the 42 months that the case lasted.

> *The Washington Monthly*
> (January/February 1998)

About 30 representatives from "state regulatory agencies, health plans, indemnity insurers, consumer advocate organizations, business group, and health-care professionals" in Minnesota are working to introduce legislation "that would create what could be called the state Office of Health Care Consumer Advocacy and Information."... Apparently it has a relatively good chance of being enacted.

> *St. Paul Pioneer Press* (14 January 1998)

Many seniors with Medicare supplemental insurance through the AARP will see a 13% average increase in monthly premiums in 1998.... The Medigap rate increases have been approved in more than 40 states, including Connecticut (12%), Rhode Island (21%), Arkansas (16%), New York (15%), California (11%) and Florida (12%).

> *Wall Street Journal* (19 December 1997)

Drivers Ed 101?

A driver's ed teacher in Durham, NC, was suspended for instructing a student driver to chase after a car that had cut them off and then punching the offending driver in the nose.

> *The Washington Monthly* (December 1997)

The United Seniors Association, a group representing 500,000 senior citizens, filed suit in federal district court December 30 to block a new law (Section 4507) that requires doctors who contract privately with Medicare patients to forego Medicare payments for two years.... Sandra Butler, president of the association, contends that "the law would destroy seniors' ability to pay the doctor of choice, for the service of their choice, without the interference of the federal government."

> *New York Times* (31 December 1997)

"On the day before your 65th birthday you can choose your own health care; on your 65th birthday and after, Section 4507 of the Medicare law means the government chooses it for you."

> U.S. Senator Jon Kyl's aide, Jade West, in supporting the repeal of Section 4507.

Only in America: A bus carrying five passengers was hit by a car in St. Louis in December.... By the time police arrived on the scene, however, 14 pedestrians had boarded the bus and had begun to complain of whiplash injuries and back pain.

> *Internet* (6 January1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Should the City Medical Societies Take an Active Part?

Letter to the Editor: So far, Connecticut's physicians have persevered admirably in defending the professionalism of its physicians and in protecting the health- care rights of its citizens. Eliminating gag clauses and instituting independent appeals mechanisms for patients are just a few of the achievements that resulted from collaboration between our county medical associations and the Connecticut State Medical Society. And the physicians and administrators who worked hard to move the issues forward to our legislators are deserving of our thanks.

However, our political effectiveness would be even greater if our city medical Societies took on a more active role. Many of them limit their functions to such activities as dinners with guest speakers and granting scholarships. Some of the more active ones educate the public about domestic violence or the dangers of smoking. All of these are worthwhile and should continue, but in these uncertain times it behooves our local medical societies to take on a broader political role.

They have several advantages to assist them in doing this. For example, they can be convened rapidly when necessary; attendance is convenient because they are close to home, and members are likely to have social affiliations and friendships that facilitate rapport with local employers, legislators, managed-care executives, hospital administrators, and other health-care professionals. Creating networks like these where information is shared with a diversity of professionals helps to build consensus.

If physicians are to be as effective as they can be in shaping health-care policy they must be as educated as much as possible in the process; and it is the responsibility of organized medicine to provide the "schools" where they can get that education.

What better place than our city medical societies?

In them new physicians learn how to articulate their viewpoints; and in them they learn the give-and-take of political interaction with their colleagues. Indeed, I can think of no better place than our city medical societies for physicians to begin learning the political skills they will need if they are to participate effectively at the county and state levels.

This is an important issue and the leadership of the CSMS should discuss/consider it at their house of delegates meeting in the spring.

Edward J. Volpintesta M.D.
Member, Board of Trustees,
Fairfield County Medical Association
President, Danbury Medical Society
Bethel

In Response to *Physician Assisted Living* (PAL)

Letter to the Editor: The December issue of *Connecticut Medicine* confined chiefly to the concept of Physician Assisted Living (PAL) is an important and timely contribution to the dialogue concerning end-of-life, chronic debilitating, and painful disease states and their effective management. There is a need to incorporate the hospice concept of care into main-stream medicine. Our institutions including hospitals and nursing homes must alter case management to include the 10 principles of PAL.

Our state and national political representatives, the attorney general, prominent medical and public health educators, and a noted theologian are among contributors to this special issue. That there is a broad spectrum of interest and support for PAL is encouraging at a time when changes in the attitudes of society, the medical-care system, and the political leadership are being sought in order to ameliorate conditions for those in chronic pain and at terminus from illness.

Strong endorsememt of PAL is necessary to avoid widespread acceptance and promulgation of physician assisted *death,* a concept accompanied by the necessity to develop bureaucratic rules and regulations for its governance and administration that could be altered to promote the genocide of the elderly ill and disabled nonproductive others in our society by the politically powerful. Callous, inhumane, and deadly disposal of unpopular minorities is a phenomenon that is part of our 20th-century history as exemplified in Germany, Russia, and China during and after World War II.

It is essential, also, that our major health-care institutions initiate committees with the responsibility for the training and oversight of those working in PAL including physicians, nursing personnel, and volunteers. The physician cadre should include those with a background in issues of acute and chronic pain management. One of the major impediments to efficient and compassionate management of painful conditions has been the draconian oversight of the use of opioid medications by the Drug Enforcement Administration (DEA). The support of the legal, political, and religious sectors for PAL is important for rational programs of opioid administration that recognize the development of drug tolerance and the need for increasing the frequency and potency of opioid dosing as physiological rather than a manifestation of drug abuse or dependency.

These issues can only be helped by the current Connecticut legislation under consideration by the Judiciary Committee of the General Assembly of House Bill 6991, which includes the stipulation that health-care related licensure must be accompanied by successful completion of training related to substance abuse prevention, diagnosis, and treatment. Such training would provide pharmacological information in depth concerning the use of drugs of the opioid class.

In summary, *Connecticut Medicine* is to be congratulated for its signal contribution to health care in its presentation of this important issue at this time. It should be widely disseminated.

Henry N. Blansfield, M.D.
Member, American Society of
Addiction Medicine Advisory Board,
National Alliance of Methadone Advocates
Danbury

In Response to *the Physicians Assisted Living: The PAL Partner Initiative* Article

Letter to the Editor: The article "Physicians Assisted Living: The PAL Partner Initiative" in the December issue presents the history of the hospice movement in this community. As a member of the "small group of visionaries" who met frequently for many years, I recall the activities of this group that led to the founding of the Connecticut Hospice in Branford in 1980.

The initial interest in considering the need to improve services for patients and their relatives during the last phase of life began in 1963 when Dr. Bernard Lytton, professor of surgery invited Dr. Cicely Saunders whom he had known since his hospital work in London, to visit Yale School of Medicine.

Dr. Saunders's deep commitment to the provision of spiritual support and improvement of pharmacological treatment for patients during the terminal phase of life soon was recognized throughout the world. She also stressed the need to provide support to close relatives as they dealt with the loss of a loved one. Her presentation at Yale attracted a large number of medical students, who at the conclusion of her lecture jumped to their feet with a standing ovation. Returning to New Haven in 1966 for six weeks as a visiting professor in the Yale School of Nursing, Dr. Saunders again was well received. In 1967 she received an honorary degree at Yale University.

In 1967 Dr. Saunders opened St. Christopher's Hospice in London. Florence Wald, upon completing her second term as dean of the Yale School of Nursing traveled to London to visit this new institution. In 1968 she returned for a month long visit to St. Christopher's Hospice.

In 1968 a chance meeting on the street with Rev. Edward Dobihal, Dean Florence Wald, Dr. Raymond Duff, and myself resulted in our having lunch together. We discussed in detail the need for improving services for patients and families during the terminal phase of life.

In 1969 Rev. Edward Dobihal, Director of Religious Ministries at Yale-New Haven Hospital spent six months at St. Christopher's Hospice while on a sabbatical leave.

Florence Wald subsequently invited me to join a diverse group of caregivers meeting regularly at the medical school to study the available services and the unmet needs of patients and families during the terminal phase of life and after the death of the patient. Dr. Ira Goldenberg was an active participant.

These discussions were an oasis for me in the whirlwind of my daily activities as a practicing pediatrician. Very quickly, despite diverse professional and religious backgrounds, we were drawn together by a common reverence for improving services for patients and their families facing the tragic loss of a loved one. It was at these meetings that I first met Dr. Elizabeth Kubler-Ross and Dr. Cicely Saunders during their visits to New Haven.

Our discussions led to the inauguration of a Hospice Home Care Service in 1974 and to the construction of the Connecticut Hospice in Branford which opened in 1970. This building was the first in the country planned and constructed specifically for serving terminal patients and their relatives. The Connecticut State Medical Society responded enthusiastically when Dr. Saul Milles and I approached the officials for support of this project.

I learned from my participation in these discussions that I had paid little attention to serving children and parents in my pediatric practice as they experienced tragic losses. I began to reach out to families at these sad moments. Parents, children, and adolescents as they became aware of this interest soon began to seek the support of my partners or myself as they experienced the loss of a loved one.

Morris A. Wessel, M. D.
New Haven

Rosemary Hürzeler Johnson, R.N., M.P.H., H.A., President and CEO, The Connecticut Hospice, Inc., responds: The Connecticut Hospice, Inc., recently rededicated its children's program as *The Children's Place.* With over 10 years of experience in caring for children with an advanced irreversible illness, they stand ready with their well-designed pediatric center, to provide comprehensive care through their home care and inpatient center.

Dame Cicely Saunders, O.M., D.B.E., F.R.C.P., founder of the modern hospice movement, was the keynote speaker at the *Unveiling of a Symbol* ceremony, honoring state legislators, at The Connecticut Hospice on 20 October 1997. This symbol, the tree of life, was designed and sculptored by a family member in memory of his daughter.

In Response to Dr. Maria Lenaz's *Letter to the Editor,* "Ethics in Managed Care"

Letter to the Editor: The letter by Maria Lenaz, M.D., regarding the ethics in managed care is a deeply flawed analysis by someone who should know better.

Medical ethics are rooted in morality and law and long tradition. Managed care should not be having any effect on it at all. The fact that the physician is an employee, regardless of whom the employer may be, should have no effect at all on his obligation to the patient. If there is a conflict between his employer and the needs of the patient it would be unethical to do anything that would harm the patient.

Managed care is simply a device to divert money from doctors and patients to third parties and is intrinsically wrong. Resource allocation has always occurred throughout the history of medicine, but resource allocation does not mean diversion of funds to stockholders.

To claim that the principles of medical ethics are not absolute and then to reference an article which appeared in *HMO Magazine* is not exactly how I would determine what is ethical or not.

Health maintenance organizations are intrinsically wrong because they violate the confidentiality of the doctor-patient relationship. Insurance was never meant to be the cash cow to pay all expenses. Historically, the concept of insurance was to provide for catastrophic events through risk sharing. It is a perversion of the principle of insurance to have corporations make a profit through the misery of others. It is a violation of medical ethics for doctors to fail to hold sacred those things which occur in the context of the confidentiality of patient care.

There are many mechanisms which could be used to maintain confidentiality and still have oversight regarding quality and financial honesty. The insurance industry has consistently failed to allow the use of codes which would protect confidentiality, but instead have set up systems to share medical information in a way which is totally unethical and which could never be excused.

James R. Merikangas, M.D.
Woodbridge

Letter to Editor: I read Dr. Maria Lenaz's *Ethics in Managed Care* letter in Nov. *Connecticut Medicine* twice and even then, wasn't sure I understood it. I finally decided it was an intellectually worded *Apologia* for HMOs. I also found my heart beats to a different drummer.

Dr. Lenaz asserts managed care is here to stay. I'm not so sure; I am optimistic enough to think the pendulum has swung about as far as it can and perhaps the harbingers of reversal are in the winds!

I believe the average physician has *always* embraced the ethical challenge of providing the best possible care for individual patients. The problem is with her qualifying phrase, "within the limits of the resources available for the entire HMO population ..." Dear reader, substitute the word "money" for this phrase. If CEOs of HMOs were not being paid more in salary and options than the average physician makes in a lifetime and if stockholders weren't making money from "profits," would be more "resources" available for patient care. The "ethical" problem here is within and created by the HMOs; physicians are merely being dragged along and into it; we solved ours a long time ago.

Why do you think the physician union movement is growing? It is not because most physicians have an ethical deficit. It is because the "system" has long since disposed of the fat and is increasingly attacking the muscle and bone. Perhaps even more accurately, the "fat" has been transferred to the pecuniary interest of administrative HMO executives and stockholders.

Robert C. George, M.D
Norwalk

Letter to the Editor: There are logical flaws in Dr. Lenaz's *Letter to the Editor* (*Connecticut Medicine* 1997; 61:753). She cites "five ethical-principles ... autonomy, nonmaleficence, beneficence, justice-equity, promise keeping-truth telling." She says "None of these principles is absolute," itself an absolute statement. Therefore she maintains the relativity of truth, justice, and autonomy. As medical director of Oxford Health Plans, Dr. Lenaz advocates a flexible ethical policy for contemporary physicians.

As a physician should I not always and absolutely seek truth, keep promises, strive to be just, avoid harm and do good? Shall I call the gatekeeper to find out if such HMO resources have been exhausted "for the entire HMO population" when I need to evacuate an acute epidural hematoma? Should I be concerned about "the entire HMO population" when I am immediately responsible for the well-being of my individual patient? Would Dr. Lenaz herself submit to the same conditional rules and flexible ethics that apparently apply to every other Oxford patient? Are CEOs held accountable when patient premiums provide their yachts? What grievance procedure corrects the amorality of their greed? Flexible ethics works well for these robber-barons. Dr. Lenaz's argument: "Because managed care is here to stay, physicians and patients must learn to understand it and develop methods to work with it" robs both physicians and patients of autonomy. Nazis believed the Third Reich was "here to stay" for a thousand years, and sought to control territory from Iberia to Siberia. Where are the Churchill's of medicine? Why are most of our fellow physicians silent? You, Dr. Massey, quote Cicero: "The short period of life is long enough for living honorably." Since failed senators were strangled to death in the basement cells of the Roman Forum, Cicero put his life on the line when he defended the autonomy of the Roman Republic. He was put to death for his opposition to tyranny. Cicero said "Socrates brought philosophy down from the heavens and into the houses." The preSocratic philosophers were known for their concern with the physical universe, while Socrates focused on human dignity. Socrates's ethic was unconditional, even to his death. Ethical truth is as old as the hills. In the words of Dr. Keating: "It rests with us to regain the high moral ground. Our profession demands it, absolutely."

Charles W. Needham, M.D., F.A.C.S.
Norwalk

In Response to Dr. Richard Evans's *Update on Childhood Asthma*

Letter to the Editor: The recent discussion on the future direction of medicine by Dr. Richard Evans on allergy and asthma (*Conn Med* August 1997; 61:470-1—reprinted from the *Western Journal of Medicine* May 1997; vol. 166, no. 5) is misleading. Dr. Evans includes a discussion of food elimination under future treatment of childhood asthma. I think he intended this to be only for treatment of food allergy and eczema for which there is evidence that elimination of foods early in life may be efficacious. There is no evidence that is systematic to my knowledge that elimination of foods has any impact on ongoing chronic inflammatory disease such as asthma. This misleading comment needs to be rectified.

A similar misleading statement has been made in the *Hartford Courant* and has been commented on by Andrea Apter, a professor of medicine in allergies at the University of Connecticut School of Medicine. Please rectify this misleading comment that food allergy impacts on chronic asthma.

Christopher Randolph, M.D.
Allergy/Asthma/Immunology

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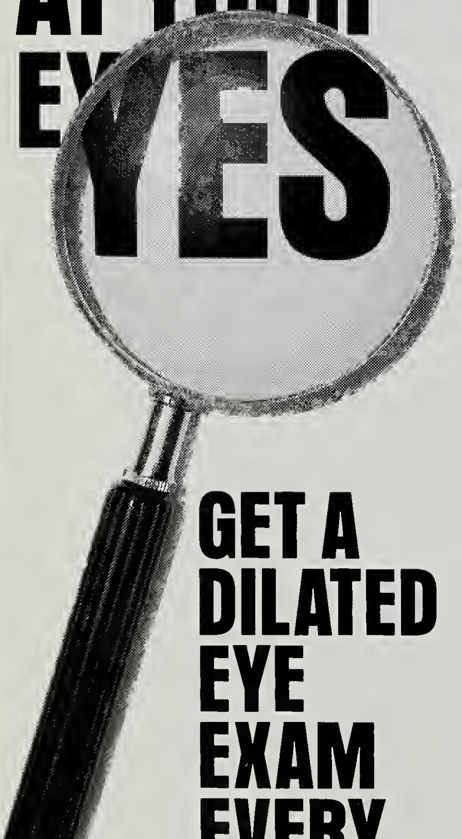

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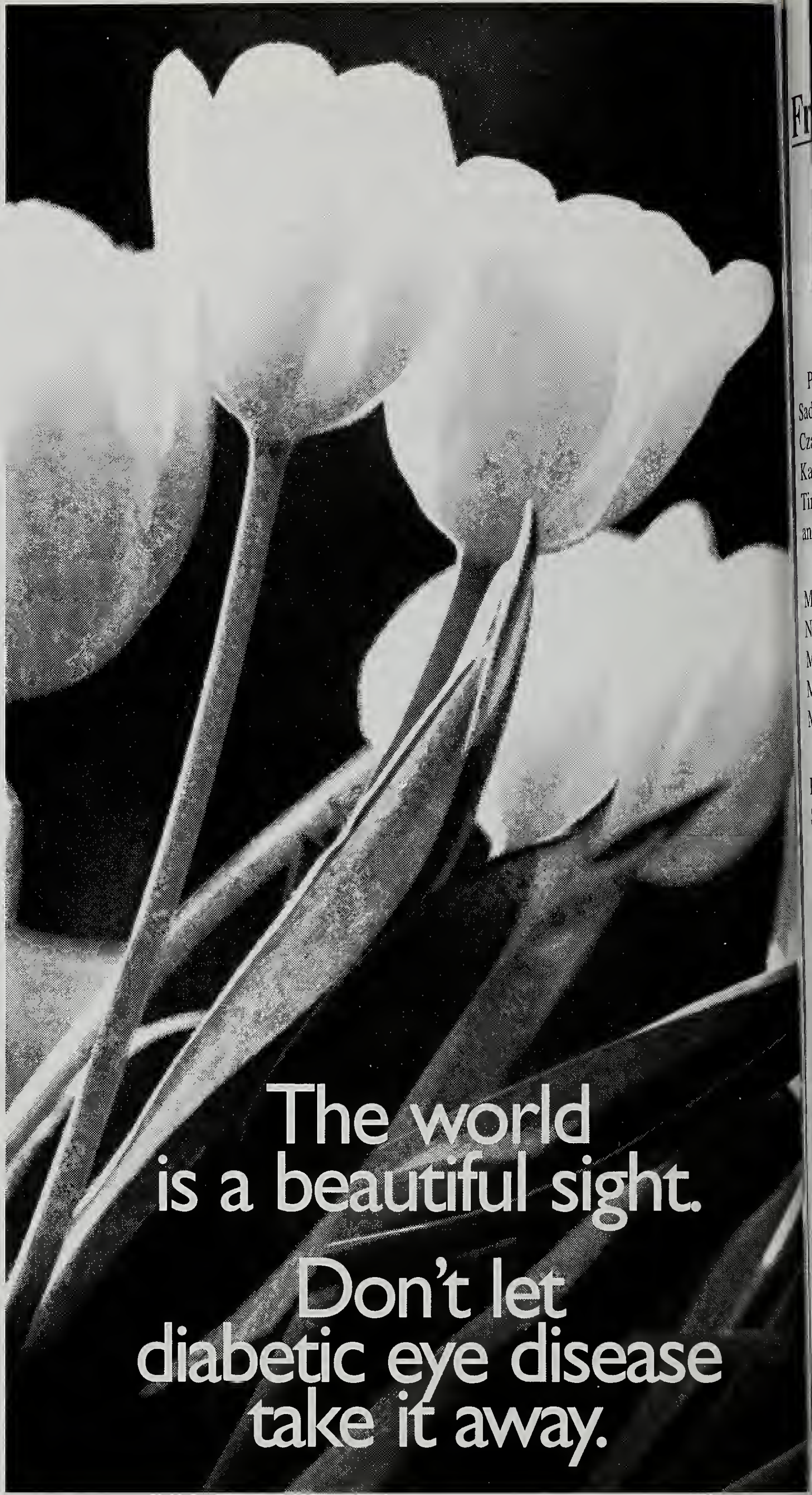
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From the Executive Director's Office

COUNCIL MEETING

Thursday, 22 January 1998

Attendance

Present, in addition to the chairman, Dr. Joseph Sadowski, were Drs. Ahamed, Beck, Bigos, Bobruff, C. Czarsty, Deren, Eslami, Franklin, Geary, Herzog, Hollister, Katz, Keating, Maloney, Mushlin, Scarpa, Sosa, Timmerman, Van Linda, Watson, Wetstone, Wolfson, and Zeppieri.

Also present were: Drs. Genel, Thompson, Mr. Norbeck, Ms. Lindquist, Mr. Brunell, Ms. Morelli, Ms. Schaffman, Norbeck, Mr. Staples (all CSMS staff), Mr. Thompson, Ms. Phillips, (FCMA staff), Ms. Debiase (NHCMA staff), Mr. Fiorentino, (HCMA staff), Ms. Snider (New London, Middlesex and Windham Counties staff).

Absent were: Drs. Brooks, J. Czarsty, Fischbein, Handelman, Lesnik, Montegut, Narayanan, Redmond, Schwartz, Sindwani, Tesoro, and Wesler.

Robert R. McDonnell, M.D.

The Chairman called for a moment of silence in memory of Robert R. McDonnell, M.D., CSMS Treasurer, who died on 11 December 1997.

Reports of Related Organizations

CSMS-IPA: Dr. David Thompson, Jr., President of the CSMS-IPA, stated that he wished to review the relationship between CSMS and the CSMS/IPA. It was reported that the CSMS/IPA was initiated by CSMS and was given certain missions. The CSMS-IPA has been true to its mission of creating an organization based on the mandates established by the CSMS for its formation, ie, open access, any qualified provider, no capitation, total physician control.

The Board of Directors of the CSMS-IPA is 100% physicians. A total of 27 voting members, 16 representatives from the counties, eight representatives appointed by the CSMS Council, three officers of CSMS (president, president-elect and vice president). He stated that this gives CSMS and its counties total control. He reported that as president, he had made presentations to almost all of the Council and House of Delegates meetings and sought the input of these groups .and was pleased to have the opportunity to discuss the issues with these groups. He stated that criticism is expected and there are probably some physicians who would not like to have any HMOs, but the CSMS-IPA goal is to create a situation where managed care follows the dictums and the mission of the Connecticut State Medical Society and be competitive and provide cost-effective medical care for its members.

He reported that the Bylaws of the CSMS-IPA make it very difficult to amend them. More than 50% of all physician members must vote and more than two-thirds of the votes must support the change. Getting physicians to vote in a timely fashion is extremely difficult. In 1996, the necessary numbers voted to make a bylaw change, which then should have been presented to CSMS to approve, as the sole shareholder. The bylaw change which in effect would eliminate the limitations on the number of terms that a director of the corporation may serve was presented to the Council at the 3 December 1997 meeting and was tabled until the January meeting.

It was reported that on a related issue the CSMS-IPA has been involved with discussion with M.D. Advantage concerning that organization working with the IPA to provide it with infrastructure and a business plan, They have concluded their initial contact with M.D. Advantage and they are working with the IPA as they seek to try to improve things. The responsibilities of the IPA keep continually growing and working forty hours on the IPA plus a full time practice is stressful and he believes bringing in an executive director and getting some infrastructural support from M.D. Advantage will allow them more time to communicate with the membership. He then asked that the resolution concerning the amendment re terms of directors, tabled at the last meeting be approved.

Communication Re: IPA from New London County Medical Association

A letter from the president of the New London County Medical Association stating that the relationship between the CSMS-IPA and M.D. Health Plan may not be in the best interests of the physicians of Connecticut was distributed with the agenda. Dr. Thompson, president of the CSMS-IPA, distributed a reply to that letter. He reported that for many years, he had the opportunity to make a presentation at the annual and semi-annual meetings of the NLCMA and was disappointed when these presentations were removed from the agenda. He recently asked if they would reinstate the CSMS-IPA reports at their meetings and was told that they would reinstate his giving reports. The main thrust of the letter from the NLCMA concerned a term "aggressive utilization of the physician profiling system to identify and correct the behavior of physicians whose utilization and cost patterns are inconsistent with those of their peers." Dr. Thompson gave a detailed report on the relationship between the IPA and M.D. Health Plan and the other questions in the NLCMA letter. Future reports to that organization should clarify the issues raised.

M.D. Advantage

Dr. Michael Deren, chairman of the M.D. Advantage board, reported that there are several physician networks considering a "partner" relationship through M.D. Advantage and extensive discussions continue with physicians in Fairfield, Hartford, and New Haven counties. There have also been a number of hospitals that have provider and service organizations expressing interest in considering an M.D. Advantage relationship. All of these groups have requested confidentiality of their initial discussions.

He reported on a retreat held by M.D. Advantage on 14 December 1997. At that meeting, items such as: the regional MSO structure and services, its relationship to CSMS and MED3000, and a flow of revenues between the physician groups, M.D.Advantage, and the regional MSO were discussed.

There are several objectives established for M.D. Advantage. The most important objective was to prepare a business plan for 1998. This plan will incorporate all aspects of marketing and development of services to members of CSMS and to coordinate with the regional MSO, Health Care Solution of Connecticut. Dr. Deren reported that Mr. Darnell had suffered a myocardial infarction and had to have open heart surgery. There has been some delay due to the unfortunate circumstances surrounding James Darnell; however measures are being taken to continue M.D. Advantage progress in achieving its objectives for 1998. He stated that he believed that their relationship with the CSMS/IPA was growing.

Report of the President

Dr. Keating reported on the untimely death of Dr. McDonnell, CSMS Treasurer, which left a vacancy in a critical position. With the advice of the Chairman of the Council, he asked Roger Beck, M.D., a long standing member of the Fiscal Subcommittee, to assume the post of Interim Treasurer and Dr. Beck agreed to serve in that capacity. The bylaws require that the Council appoint a member to fill vacancies created until the meeting of the next House of Delegates. It was VOTED to approve Dr. Keating's motion that Dr. Beck be appointed to serve as treasurer until the meeting of the House of Delegates.

As a fall-out of the Sunbeam and AMA issue, Dr. Keating wished to bring to the attention of the Council that CSMS and the county organizations from time to time embark on educational activities and accept financial support from various agencies to support those educational activities Currently CSMS, Fairfield and Hartford Counties are sponsoring a Smoking Cessation Workshop and it is supported by Glaxo Wellcome, which firm markets a drug to stop smoking. There is no intent at the workshop to endorse or market this drug. This issue was raised by members of the Public Affairs Committee. He stated in the absence of any objections, he considered the Council informed and approving this concept.

A copy of the form for nomination for the CSMS Distinguished Citizen Award was distributed to Council members and Dr. Keating asked that Council members give it some consideration.

He stated that he has received many questions as to what the CSMS is doing about delayed payments to physicians from managed-care companies and that these complaints should be directed to the State Department of Insurance, which agency is overseeing the managed-care bill. The CSMS Legislative Committee is seeking legislation to help enforce prompt payment.

Report of the Executive Director

Mr. Norbeck reported on the following items:

The city of Chicago will operate the country's first city-based managed-care consumer protection office. The office will collect data from managed-care organization, receive and investigate consumer complaints and if necessary, pass them on to the Illinois Department of Insurance, which regulates HMOs.

A coalition of business groups will unveil a year-long one million dollar ad campaign aimed at the slew of anti managed care bills now before Congress. The ads will target the D'Amato and Norwood bills which would make it easier for patients to sue health plans.

The National Labor Relations Board (NLRB) rejected a labor union's request to represent hundreds of New Jersey physicians who argued that HMOs have become their employers, controlling their working conditions, medical decisions and income. The National Labor Relations Board ruled that the physicians did not meet the definition of employees under the NLRB Act. Factors favoring employee status for the doctors are substantially outweighed by those favoring a finding of independent contractor status. The decision is being appealed to the NLRB in Washington.

A new survey by the Kaiser Foundation and Harvard University shows that significant majorities of the American people favor the measures intended to protect patients in President Clinton's proposed patient Bill of Rights. While 74% favor the consumer "Bill of Rights" and only 17% opposed it, support dropped materially when possible negative effects of the bill were mentioned.

According to new ABC/*Washington Post* poll, 62% of Americans support President Clinton's proposal to all near-elderly persons to buy into Medicare at age 62; 56% support letting laid off employees buy Medicare coverage at age 55 at about $400 per month.

Federation Coordinating Team.—Mr. Norbeck reported that the Federation Coordinating Team (FCT) was created out of a study of the Federation in the summer of 1996. He was named to the FCT in July 1997. There are 27 members on the board, 23 physicians and four staff persons. The FCT meets about five weekends a year at AMA expense. The mission of the FCT is to increase the value of organized medicine, define that value by physician needs, not organization needs, and maximize federal resources. The FCT vision is to promote a sense of community within the Federation with emphasis on improved communication, coordination and collaboration.

FCT is now working on a web page as a communication site for medical society leaders with the Federation. It is examining the overlap of responsibilities of the various facets of the Federation; but it is a very sensitive area. A survey to leaders in the Federation is being developed and will be sent out in hopes of getting a full perspective on how that overlap is viewed and how those leaders view the roles and responses of their respective organizations.

Report on AMA Annual Meeting
7–10 December 1997, Dallas

Dr. John Franklin showed a video tape taken at the meeting.

Distributed with the agenda was a written report on the AMA meeting submitted by Dr. Edward Kamens, which was received as information.

Dr. Frank Scarpa commented that this was his first meeting and was impressed as to the democratic operation of the organization. He reported that he felt that it was important to get young physicians involved in organized medicine.

Following discussion concerning participation of students and residents in organized medicine, it was VOTED that an Ad Hoc Committee be appointed by the Chairman of the Council and that committee bring back a definite plan to reactivate student and resident participation.

Resolutions Referred by House of Delegates

a) "Creation of CSMS Managed Care Patient Advocacy Committee"

Resolved, that the Connecticut State Medical Society establish a managed care patient advocacy committee with the following functions:

- To act as an advisor to physicians in the appeals process created by a substitute House Bill #6883, as amended.
- To expedite quality, access and fairness.
- To engage the Department of Insurance and the Department of Public Health of Connecticut to work in concert with the CSMS to assure physicians input into implementation of House Bill #6883.
- To receive, collect and research information concerning problems within the managed care industry.
- To report to the House of Delegates and Council when appropriate.

It was VOTED that the Chairman of the Council appoint the committee and that Dr. Timmerman be named chairman and that the committee be composed of 11 members including the chairman. It was suggested that some of the members who served on the Healthcare Reform Task Force be considered for membership on this committee.

b) "Lengthen The Duration of the House of Delegates"

Resolved, that the House of Delegates of the Connecticut State Medical be extended to at least a full day, in order that sufficient time may be given to properly examine and discuss items of importance to the medical profession.

The House was informed that a survey was underway concerning the House of Delegates meeting and the House referred the resolution to the Council until the study was completed and report back to the House of Delegates annual meeting in 1998.

A copy of the results of the survey was distributed to the Council and the responses indicated that they did not wish to lengthen the meeting. After lengthy discussion, it was VOTED that the chairman of the Council, the president and president-elect discuss with the speaker and vice speaker ways and means to attract more delegates to the meeting.

Legislative Update

In the absence of David Parke, M.D., Chairman of CSMS Legislative Committee, Mag Morelli, Director of Government Relations, gave a comprehensive report on potential issues facing CSMS in the 1998 Legislative Session. A package listing 26 potential issues with supporting material had been distributed to the members of the Council. Some of the more important issues discussed were HMO Delayed Payments, Patient Confidentiality, APRNs Proposal for Independent Practice, Physician Profiles, and Licensure of Provider Sponsored Organizations.

Another issue that was discussed was facial surgery which always seems to be classified as cosmetic surgery and not paid for by HMOs. Ms. Morelli outlined a method, ie, pictures of facial abnormality, that possibly might meet the criteria of HMOs and be approved as medically necessary facial surgery. It was VOTED that Ms. Morelli be authorized to move ahead with legislative intent as she outlined.

It was VOTED to accept the report of the Legislative Committee.

Committee on Workers' Compensation

Dr. Joseph Zeppieri, Chairman of subject committee, distributed the minutes of a committee meeting held on December 16, a letter to Jesse Frankl, Chairman, Workers' Compensation Commission dated 27 March 1996, and two letters from the National Recovery Council. He reported on the committee's dissatisfaction with negotiations to date and submitted the following recommendations:

1. A letter should be sent to the Governor, Chairs and Ranking Members of the Labor and Insurance Committees, the Central Labor Council, and the Attorney General with a copy of the letter dated March 27, 1996 regarding the medical protocols The letter should state dissatisfaction with both the protocols and the Chairman's lack of response to our 1996 letter. The letter should reflect the Committee's concern that there is a general disregard that the office of the Chairman has for Connecticut workers.
2. A letter should be sent to the Labor Committee Chairs regarding the Chairman's disregard of physicians' concerns. The Committee would like to include specific reference to the comments the Commissioner made to CSMS representatives regarding our "bad docs" during a public hearing, asking when we were going to help him get rid of them. CSMS responding in writing that we would be more than willing to have our county peer review committees review any complaints involving workers' compensation treatment. The letter should also reference the Chairman's disregard of the Committee's concerns regarding the billing guidelines and bill review practices of the workers' compensation carriers.
3. A request should be sent to the Labor Committee asking for a review of the Chairman's procedures regarding approval of the Medical Care Plans. CSMS should also request that the Labor Committee ask for a review of the approved medical care plans experience now that it has been two years since the first plans were approved.
4. CSMS should submit to the Labor Committee a proposal for legislating managed care reforms for Workers' Compensation medical care plans.
5. CSMS should explore the possibility of bringing a class action suit against the workers' compensation carriers.

It was VOTED approve all five recommendations.

Vice President

Dr. Stuart Mushlin, vice president, announced that he has accepted a position outside of Connecticut and would not be able to accept the position of president-elect. Dr. Scarpa announced that Dr. Mushlin made the announcement at the Fairfield County Medical Association Board meeting and this information was accepted with regret. Fairfield County Board voted to submit the name of Stephen Katz, M.D. as a successor to Dr. Mushlin and Seyed H. Aleali, M.D. as a replacement for Dr. Katz. It was VOTED to submit this information to the Nominating Committee, since Dr. Mushlin will be in Connecticut until 1 July, and these changes will take place at the annual meeting in May.

Date of Future Meetings

Council Meeting—Wednesday, 18 March 1998
Annual Meeting—House of Delegates,
Wednesday, 13 May 1998

Connecticut State Medical Society Responds to AMA-Bashing

Editorial Page Editor, *The New York Times:*

The "revelations" in your 2 December article, "After Bad Year for AMA, Doctors Debate Its Prognosis," really aren't at all surprising. Physicians are an independent lot, as might be expected of committed professionals. Their greatest individual strength, each doctor's independent judgment, may also be their medical organizations' greatest weakness. While it is true that only some 40% of *all* the country's physicians are AMA members, that percentage is higher for *practicing* physicians—those who are actually involved in direct patient care—and higher still for private practitioners, as your author well knows, since she used that figure (90%) for comparing 1966 AMA membership. By comparison, only about 10% of nurses, with their own independent bent, belong to their national organization. Labor unions attract less than 20% of employed workers.

The AMA House of Delegates, which may be the most democratic body in America, entertains resolutions twice yearly and hears testimony from nearly any physician in the country who chooses to be heard. But after extended debate, some matters are watered down for the sake of reaching consensus, a process that can be difficult to rally behind, and is undoubtedly frustrating to those with specific agendas.

The author is right in suggesting that the demographics of the AMA House do not closely conform to the overall membership, but that is not the AMA's doing. It is the local, state and specialty medical societies that choose their AMA delegates to represent *them,* not the AMA. Nevertheless, changes are being made to improve those demographics, so that underrepresented constituencies will have more of a voice. Author Zuger criticizes the average age of delegates as unrepresentative of younger physicians. However, a seat in the AMA House is often a reward for long and fruitful medical society leadership at the local and state levels, and as in any governing body, experience in office is an advantage. Furthermore, older practitioners may have less pressing family responsibilities and can more easily leave their practices for extended meetings than their younger colleagues.

Perhaps it is the AMA delegates' politics and not their ages that Ms. Zuger finds wanting. It is interesting to note that practically all the critics of the AMA she quotes are either distinguished medical journalists or medical educators, not practicing clinicians like most AMA members.

All of us, who are or who one day will be real patients, should hope for a strong and vibrant AMA, because the capturing of American medical decision-making by commercial and governmental fiscal intermediaries does not bode well for us. The AMA and its activist physicians constantly oppose those intrusions into the hallowed patient-physician relationship. Sadly, they may soon be the *only* powerful advocates that patients have left.

Timothy B. Norbeck
Executive Director,
Connecticut State Medical Society

The Physician Health Program

1792

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- ◆ The **PHP** recognizes that most people may not know what to do when they suspect that a physician may be impaired, or how to help him.
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The **Physician Health Program**
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Connecticut State Medical Society

For more information or to call in
confidence, contact the **PHP** at
(203) 865-0587 or 1-800-635-7740

Neil J. Grey, M.D.
Medical Director

Michele R. Norbeck
Director

CORRECTIONS

In the December Special Issue of *Connecticut Medicine* **Connecticut Hospice—Commemorating Physician Assisted Living—25 Years Educating Caregivers,** the following corrections should be noted:

In the last paragraph of "Physician Assisted Living: Medical Educators' Perspective" by Gerald N. Burrow, M.D., *Special Advisor to the President Levin on Health Affairs and Former Dean of the Yale University School of Medicine* should have read as follows:

> Physician Assisted Living is in its infancy. We now have the ability to build upon Physician Assisted Living and the educational program to expand it for the medical profession and the medical schools throughout this country.

The article "What Others are Saying about PAL and Hospice" written by Lewis L. Levy, M.D. on page 786 was inadvertently left out of the *Table of Contents.*

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

STATE OF CONNECTICUT
CONNECTICUT MEDICAL EXAMINING BOARD

IN RE: PETITION SUBMITTED BY TERESA PETRICCA, PRESIDENT OF THE AMERICAN ELECTROLOGY ASSOCIATION, ON USE OF LASERS FOR HAIR REMOVAL BY HEALTH CARE PROVIDERS OTHER THAN LICENSED PHYSICIANS

DECLARATORY RULING

In November of 1998, Teresa Petricca, President of the American Electrology Association, requested the position of the Connecticut Medical Examining Board ("Board") as to whether lasers may be used for hair removal by anyone other than a licensed physician in this State.

Pursuant to Connecticut General Statutes §4-176 and Regulations of Connecticut State Agencies §19-2a-31, the Board ruled that it would hold a hearing and issue a declaratory ruling in response to Ms. Petricca's petition. The declaratory ruling proceeding was intended to address whether health care providers other than licensed physicians can use lasers for the purpose of hair removal. By law, the Board's determination on this issue is binding upon those who participated in the hearing and may also be used by the Board, on a case by case basis, in future proceedings.

A hearing was scheduled and held on August 19, 1997, and September 16, 1997. Prior to the first day of hearing, the following organizations were granted party status: American Electrology Association, ThermoLase Corporation, and the Connecticut State Medical Society. The Connecticut Society of Eye Physicians was granted intervenor status. The Board received oral and written testimony from parties and persons otherwise authorized to participate. The Board conducted the hearing in accordance with Connecticut General Statutes Chapter 54 and the Regulations of Connecticut State Agencies §19-2a-1, *et seq.*

Connecticut General Statutes §20-9 provides in pertinent part:

> (a) No person shall, for compensation, gain or reward, received or expected, diagnose, treat, operate for or prescribe for any injury, deformity, ailment or disease, actual or imaginary, of another person, nor practice surgery, until he has obtained such a license as provided in section 20-10, and then only in the kind or branch of practice stated in such license.
>
> (b) The provisions of this chapter shall not apply to: ... (14) any person rendering service as a physician assistant licensed pursuant to section 20-12b, a registered nurse, a licensed practical nurse or a paramedic, as defined in subsection (o) of section 19a-175, acting within the scope of regulations pursuant to section 19a-179, if such service is rendered under the supervision, control and responsibility of a licensed physician ...

Section 20-9 provides the framework for determining whether a particular activity is within the scope of practice of medicine, The Board finds that the use of lasers for hair removal is within the scope of medical practice. The Board finds that a licensed physician with appropriate knowledge, experience, and training should assess each patient prior to and during the course of hair removal treatment with laser therapy. The Board finds that such physician may delegate the operation of the laser for hair removal to those persons listed in §20-9(b)(14) who may render service under the supervision, control, and responsibility of a licensed physician, provided the assessment of each patient is performed by the physician. The physician shall provide direct on-site supervision in the course of hair removal treatment with laser therapy.

The Board uses the following analysis to reach this conclusion: A laser is a means of manipulating light. The use of a laser to remove hair is a medical, not cosmetic, procedure. Such a procedure alters the surface of skin. A laser may cause or aggravate certain types of dermatological conditions. The process itself is more critical than the result. Laser hair removal is an evolving technology which does not currently provide permanent results. Results vary; there can be a risk of eye damage. In making this ruling, the Board is choosing to err on the side of safety to best protect the public.

A reasonable amount of time for practitioners to conform to the standards set forth in this ruling should be allowed, not to exceed nine (9) months.

Connecticut Medical Examining Board
by: Richard M. Ratzan, M.D., Chairman

Date: December 17, 1997

It's Time to Get To Know Your Legislator

We hear it all the time.
Legislators need and want to hear from physicians.

But taking the trip to Hartford is not always easy. In fact, the ride up to Hartford is not always necessary. One of the most effective ways to get to know your legislator is to meet with them in your own hometown.

WHAT DO YOU HAVE TO DO?

- It's simple! Give your legislator a call.
- Introduce yourself as a constituent and let him/her know that you would like to meet with them.
- Make a date to meet for lunch or coffee at the hospital or in your office. OFFER TO GIVE THEM A TOUR OF THE HOSPITAL or ASK THEM TO ACCOMPANY YOU ON ROUNDS.
- Bring along your spouse or a colleague.

WHAT DO YOU TALK ABOUT?

- Get acquainted. Let them know who you are and what you do. Discuss what's going on in the local medical community. Ask them to tell you something about themselves. Determine if you have any common interests. Maybe you have mutual acquaintances.
- Ask them what type of legislation they want to work on, what committees they will be assigned to and what issues they plan to face.
- Now is not the time to ask for legislation. **However, now is the time to offer your insight and experience on medical issues and the practice of medicine on a local level.**
- At the end of the appointment, make sure that you give him/her your card or send a letter (enclose your card) and let them know that you will be available if they ever need medicine's perspective or expertise on an issue.

And, of course, drop CSMS a fax (203) 865-4997,
or give us a call (203) 865-0587,
and let us know about the meeting.

WHAT IS THE VALUE OF MEETING WITH YOUR LEGISLATOR?

- Your legislator will gain insight into local medical issues and will have a valuable resource within his/her district to call for information regarding medical issues that come before the General Assembly.
- CSMS will gain a key contact in that legislator's district. This means we may call you when a grassroots contact needs to be made during the Legislative Session.

Call Mag Morelli, CSMS Director of Government Relations,
at 1-800-635-7740 for more information.

M.D. Advantage News

The M.D. Advantage—It's yours!

Physicians throughout Connecticut now have access to a full spectrum of practice management and network development services from the Connecticut State Medical Society through its physician-directed MSO (medical service organization) called *M.D. Advantage.*

As with previous challenges to the practice of medicine in our state, CSMS leaders from all the counties have responded promptly and proactively to preserve the independence and integrity of each physician's medical judgment and to protect the sanctity of the patient-physician relationship.

CSMS leaders recommend that physicians seeking administrative assistance give consideration to this newest, physician-driven MSO model.

For more information or to schedule an appointment, contact M.D. Advantage:

Sandra La Rosa
Director of Physician Services
or
Greg Pepe
Chief Executive Officer

at

CSMS, (203)865-0587 ext. 111

The Connecticut HUSKY Plan Health Care for Uninsured Kids and Youth

In late October, Governor Rowland signed into law the new *Connecticut HUSKY Plan,* which extended comprehensive health care coverage to many currently uninsured children. The Governor and State Legislators were responding to the opportunity offered by the federal "Kiddiecare" legislation, which will provide the additional funding for this program.

Basically, the HUSKY Plan targets two patient populations. The current Medicaid program for children will be renamed "HUSKY Part A," and there will be an effort to reach out to the parents of the 52,000 children, currently uninsured who are Medicaid eligible. The HUSKY Plan than extends health insurance eligibility to children whose families earn incomes too high to receive Medicaid. This new coverage will be called "HUSKY Part B" and will be available to children in families whose annual income falls between 185% and 300% of the federal poverty level. There is also a component to the plan, called "HUSKY Plus," which will provide supplemental mental and physical health coverage to children with severe behavioral and physical needs.

The HUSKY Plan begins this spring. The current Medicaid Managed Care system will remain in place, and the integration of the "HUSKY Part B " is currently being developed by the Department of Social Services. For more information on the HUSKY Plan, call the Department of Social Services at 1-800-385-4052 or write to Program Manager, HUSKY Plan, Department of Social Services, 25 Sigourney Street, Hartford, CT 06106.

A registration statement relating to the securities of Physicians Care for Connecticut, Inc., has been filed with the Securities and Exchange Commission, but has not yet become effective. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This notice shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under securities laws of such state.

PHYSICIANS CARE
FOR CONNECTICUT, INC.

Physicians Care for Connecticut, Inc. has recently filed a registration statement with the Securities and Exchange Commission relating to the proposed sale of shares of its Common Stock, representing new financing.

Physicians Care for Connecticut, Inc., was incorporated for the purpose of developing and operating a statewide IPA model HMO.

The Company's registration statement proposes the sale by the Company of:

3,000 Shares of Class A Common Stock at $4,000 per Share
and
3,000 Shares of Class B Common Stock at $4,000 per Share

(prices for Shares are subject to a prompt subscription price of $3,000 if subscription documents are received within the first 90 days of the date of the Final Prospectus relating to the offer of such securities)

For a copy of a Preliminary or Final Prospectus, please contact the Managing Underwriter, as follows:

Newbury, Piret & Co., Inc.
One Boston Place, 26th Floor
Boston, MA 02108
(617) 367-7300
(617) 367-7301 Fax

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

***Opportunities* should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians making inquiries of such *opportunities*.**

***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

Announcements on the Physician Placement Service page under Classified Advertising are charged at the regular Classified Advertising rate.

OPPORTUNITIES FOR PRACTICE

ANESTHESIOLOGY

Johnson Memorial Hospital and Johnson Surgery Center seek interested anesthesia groups in their request for proposals to provide anesthesia service at the hospital and surgery center. Direct all inquiries to: Gerard C. Buffo, M.D., Vice President for Medical Affairs, Johnson Memorial Hospital, telephone (860) 684-8164, fax (860) 684-8165.

PEDIATRICIAN

HealthFirst, a growing regional community health center with three sites in Eastern Connecticut seeks: BC/BE Pediatrician to provide a full range of preventive and primary care. All sites are fully staffed, computerized and integrated into an organizational network. Competitive salary and benefits. For more information call or send CV to: Recruitment Manager, 112 Lafayette St., Norwich, CT 06360, telephone (860) 885-1308, fax (860) 889-1982.

PRIMARY CARE

Primary care/internal medicine physician wanted for New Haven multi-specialty group. Blue Care/M.D. Health Plan affiliation a plus. Part-time, no evenings, week-ends or on call. Excellent salary. Please call (203) 795-9745.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

INTERNAL MEDICINE

Available immediately. Licensed in Connecticut. Passed National Boards. American Board certified. M.D. at Tufts University School of Medicine. Internship and residency at the Hospital of St. Raphael. Office based general internist with extensive managed care experience, seeking to join a group or associates practice. Please respond to: Michael F. Collins, M.D., 53 Cotswold Close, Glastonbury, CT 06033. Telephone (860) 633-5698.

Board eligible internist; CT license; immediate availability (locum tenens/permanent); seeking primary care office based practice setting. Prefer outpatient/clinic/urgent care. Contact: Wm. DiFederico, M.D., (203) 375-2912.

RADIOLOGY

Does your walk-in clinic need a radiologist part-time? Will travel within the greater Hartford area. Please respond to: CSMS c/o RA/BK.

PAID CLASSIFIED ADVERTISING

All PAID classified advertising orders, correspondence, and payments should be directed to: CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan Street, New Haven, CT 06511, Tel. (203) 865-0587. The Classified rates are as follows: $60.00 for 25 words or less; plus $1.00 each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy must be typewritten, double spaced, with payment, and delivered no later than the first day of the month preceding the month of issue.

LOOKING FOR PHYSICIAN TO ASSUME PRACTICE

Retiring physician looking for someone to take over internal medicine practice and/or building. Prime location in southeastern Connecticut, close to hospital and highway. Coverage available. Telephone: (860) 889-1285 / Fax: (860) 889-2109.

MEDICAL FURNITURE FOR SALE

Used medical office furniture, examination tables, ob-gyn tables, waiting room chairs, and desk chairs. Very cheap! Call (860) 651-3551.

TRANSCRIPTION SERVICES

A full-service transcription business specializing in all medical documents and reports; reasonable rates. New clients: First report free: Limit two pages. (203) 467-9701.

ATTENTION ANESTHESIOLOGISTS!!!

Don't be burdened with: Endless paper work, incorrect reimbursement from HMOs and insurance companies. Obtaining information for billing and constant follow-up with self-pay and copays. Call: **Client Contact Company** at 1-800-645-2303, e-mail: MedManCo@aol.com, or fax: 1-800-473-1184. A full-service billing and collection company.

CONNECTICUT PEDIATRIC PRACTICE FOR SALE

Beautiful coastal Connecticut town, 45 miles north of New York. Established for 11 years. No managed care. Very lucrative. Solo pediatrician with every third or fourth night coverage. Hospital with pediatric PAs and NBICU. Over 800 families on waiting list. Closed to new patients for five years. Could easily use two pediatricians. Please reply to Glenn Feole, P.O. Box 745, Westport, CT 06880; e-mail: glenn.1.feole@snet.net

CALL FOR PAPERS

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Papers prepared on a word processor should be submitted on a diskette along with the hard copy. Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

Consumer Concern Or Complaint Form Regarding Group Or Individual Health Insurance Including Managed Care Plans

To Be Submitted To
THE CONNECTICUT DEPARTMENT OF INSURANCE
CONSUMER AFFAIRS DIVISION
P.O. BOX 816
HARTFORD, CT 06142-0816

Phone: (860) 297-3900 or 1-800-203-3447 Fax: (860) 297-3872

The Consumer Affairs Division of the Department of Insurance receives, reviews and responds to complaints and inquiries from state residents concerning insurance related problems. The staff examines each complaint to determine whether statutory requirements and contractual obligations within the commissioner's jurisdiction have been fulfilled. The Consumer Affairs Division coordinates the resources available within the Department to address consumer complaints.

In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

Name of person filing the concern or complaint:

____

Address: ____

Phone where the Department can contact you: (_____) ______________________________

This concern or complaint concerns the following Insurance Company or Managed Care Plan: ______________________________

Policy Number: ______________________________

Name of Policyholder: ______________________________

Name of Enrollee: ______________________________

Name of Patient: ______________________________

Patient is ___ self ___ dependent ___other (explain)______________________________

The following is a detailed description of the concern or complaint:

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BRIEF SUMMARY

ZYBAN™ (bupropion hydrochloride)

Sustained-Release Tablets

The following is a brief summary only; see full prescribing information for complete product information.

CONTRAINDICATIONS: ZYBAN is contraindicated in patients with a seizure disorder.

ZYBAN is contraindicated in patients treated with WELLBUTRIN® (bupropion hydrochloride) Tablets, WELLBUTRIN SR® (bupropion hydrochloride) Sustained-Release Tablets, or any other medications that contain bupropion because the incidence of seizure is dose dependent.

ZYBAN is contraindicated in patients with a current or prior diagnosis of bulimia or anorexia nervosa because of a higher incidence of seizures noted in patients treated for bulimia with the immediate-release formulation of bupropion.

The concurrent administration of ZYBAN and a monoamine oxidase (MAO) inhibitor is contraindicated. At least 14 days should elapse between discontinuation of an MAO inhibitor and initiation of treatment with ZYBAN.

ZYBAN is contraindicated in patients who have shown an allergic response to bupropion or the other ingredients that make up ZYBAN.

WARNINGS: Patients should be made aware that ZYBAN contains the same active ingredient found in WELLBUTRIN and WELLBUTRIN SR used to treat depression, and that ZYBAN should not be used in combination with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion.

Because the use of bupropion is associated with a dose-dependent risk of seizures, *clinicians should not prescribe doses over 300 mg/day for smoking cessation.* The risk of seizures is also related to patient factors, clinical situation, and concurrent medications, which must be considered in selection of patients for therapy with ZYBAN.

- **Dose: *For smoking cessation, doses above 300 mg/day should not be used.* The seizure rate associated with doses of sustained-release bupropion up to 300 mg/day is approximately 0.1% (1/1,000). This incidence was prospectively determined during an 8-week treatment exposure in approximately 3,100 depressed patients. Data for the immediate-release formulation of bupropion revealed a seizure incidence of approximately 0.4% (4/1,000) in depressed patients treated at doses in a range of 300 to 450 mg/day. In addition, the estimated seizure incidence increases almost tenfold between 450 and 600 mg/day.**
- **Patient factors: Predisposing factors that may increase the risk of seizure with bupropion use include history of head trauma or prior seizure, central nervous system (CNS) tumor, and concomitant medications that lower seizure threshold.**
- **Clinical situations: Circumstances associated with an increased seizure risk include, among others, excessive use of alcohol; abrupt withdrawal from alcohol or other sedatives; addiction to opiates, cocaine, or stimulants; use of over-the-counter stimulants and anorectics; and diabetes treated with oral hypoglycemics or insulin.**
- **Concomitant medications: Many medications (e.g., antipsychotics, antidepressants, theophylline, systemic steroids) and treatment regimens (e.g., abrupt discontinuation of benzodiazepines) are known to lower seizure threshold.**

Recommendations for Reducing the Risk of Seizure: Retrospective analysis of clinical experience gained during the development of bupropion suggests that the risk of seizure may be minimized if

- **the total daily dose of ZYBAN does *not* exceed 300 mg (the maximum recommended dose for smoking cessation), and**
- **the recommended daily dose for most patients (300 mg/day) is administered in divided doses (150 mg twice daily).**
- **No single dose should exceed 150 mg to avoid high peak concentrations of bupropion and/or its metabolites.**
- **ZYBAN should be administered with extreme caution to patients with a history of seizure, cranial trauma, or other predisposition(s) toward seizure, or patients treated with other agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of a benzodiazepine) that lower seizure threshold.**

Potential for Hepatotoxicity: In rats receiving large doses of bupropion chronically, there was an increase in incidence of hepatic hyperplastic nodules and hepatocellular hypertrophy. In dogs receiving large doses of bupropion chronically, various histologic changes were seen in the liver, and laboratory tests suggesting mild hepatocellular injury were noted.

PRECAUTIONS:

General: ***Allergic Reactions:*** Anaphylactoid reactions characterized by symptoms such as pruritus, urticaria, angioedema, and dyspnea requiring medical treatment have been reported at a rate of about 1-3 per thousand in clinical trials of ZYBAN. In addition, there have been rare spontaneous postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, and anaphylactic shock associated with bupropion.

Insomnia: In the dose-response smoking cessation trial, 29% of patients treated with 150 mg/day of ZYBAN and 35% of patients treated with 300 mg/day of ZYBAN experienced insomnia, compared to 21% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.6% of patients treated with ZYBAN and none of the patients treated with placebo.

In the comparative trial, 40% of the patients treated with 300 mg/day of ZYBAN, 28% of the patients treated with 21 mg/day of HABITROL® (nicotine transdermal system) (NTS), and 45% of the patients treated with the combination of ZYBAN and NTS experienced insomnia compared to 18% of placebo-treated patients. Symptoms were sufficiently severe to require discontinuation of treatment in 0.8% of patients treated with ZYBAN and none of the patients in the other three treatment groups.

Insomnia may be minimized by avoiding bedtime doses and, if necessary, reduction in dose.

Psychosis, Confusion, and Other Neuropsychiatric Phenomena: In clinical trials with ZYBAN conducted in nondepressed smokers, the incidence of neuropsychiatric side effects was generally comparable to placebo. Depressed patients treated with bupropion in depression trials have been reported to show a variety of neuropsychiatric signs and symptoms including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. In some cases, these symptoms abated upon dose reduction and/or withdrawal of treatment.

Activation of Psychosis and/or Mania: Antidepressants can precipitate manic episodes in bipolar disorder patients during the depressed phase of their illness and may activate latent psychosis in other susceptible individuals. The sustained-release formulation of bupropion is expected to pose similar risks. There were no reports of activation of psychosis or mania in clinical trials with ZYBAN™ conducted in nondepressed smokers.

Use in Patients With Systemic Illness: There is no clinical experience establishing the safety of ZYBAN in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, care should be exercised if it is used in these groups. Bupropion was well tolerated in depressed patients who had previously developed orthostatic hypotension while receiving tricyclic antidepressants, and was generally well tolerated in a group of 36 depressed inpatients with stable congestive heart failure (CHF). However, bupropion was associated with a rise in supine blood pressure in the study of patients with CHF, resulting in discontinuation of treatment in two patients for exacerbation of baseline hypertension.

In the comparative trial, 6.1% of patients treated with the combination of ZYBAN and NTS had treatment-emergent hypertension compared to 2.5%, 1.6%, and 3.1% of patients treated with ZYBAN, NTS, and placebo, respectively. The majority of these patients had evidence of preexisting hypertension. Three patients (1.2%) treated with the combination of ZYBAN and NTS and one patient (0.4%) treated with NTS had study medication discontinued due to hypertension compared to none of the patients treated with ZYBAN or placebo. Monitoring for treatment-emergent hypertension is recommended in patients receiving the combination of ZYBAN and NTS.

Because bupropion hydrochloride and its metabolites are almost completely excreted through the kidney and metabolites are likely to undergo conjugation in the liver prior to urinary excretion, treatment of patients with renal or hepatic impairment should be initiated at reduced dosage as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible toxic effects of elevated blood and tissue levels of drug and metabolites.

Information for Patients: See PATIENT INFORMATION at the end of the full prescribing information for the text of the separate leaflet provided for patients. Physicians are advised to review the leaflet with their patients and to emphasize that ZYBAN contains the same active ingredient found in WELLBUTRIN and WELLBUTRIN SR used to treat depression and that ZYBAN should not be used in conjunction with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion hydrochloride.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions: In vitro studies indicate that bupropion is primarily metabolized to hydroxybupropion by the CYP2B6 isoenzyme. Therefore, the potential exists for a drug interaction between ZYBAN and drugs that affect the CYP2B6 isoenzyme metabolism (e.g., orphenadrine and cyclophosphamide). The threohydrobupropion metabolite of bupropion does not appear to be produced by the cytochrome P450 isoenzymes. No systemic data have been collected on the metabolism of ZYBAN following concomitant administration with other drugs or, alternatively, the effect of concomitant administration of ZYBAN on the metabolism of other drugs.

Animal data indicated that bupropion may be an inducer of drug-metabolizing enzymes in humans. However, following chronic administration of bupropion, 100 mg t.i.d. to 8 healthy male volunteers for 14 days, there was no evidence of induction of its own metabolism. Because bupropion is extensively metabolized, the coadministration of other drugs may affect its clinical activity. In particular, certain drugs may induce the metabolism of bupropion (e.g., carbamazepine, phenobarbital, phenytoin), while other drugs may inhibit the metabolism of bupropion (e.g., cimetidine).

Studies in animals demonstrate that the acute toxicity of bupropion is enhanced by the MAO inhibitor phenelzine (see CONTRAINDICATIONS).

Limited clinical data suggest a higher incidence of adverse experiences in patients receiving concurrent administration of bupropion and levodopa. Administration of ZYBAN to patients receiving levodopa concurrently should be undertaken with caution, using small initial doses and gradual dose increases.

Concurrent administration of ZYBAN and agents (e.g., antipsychotics, antidepressants, theophylline, systemic steroids, etc.) or treatment regimens (e.g., abrupt discontinuation of benzodiazepines) that lower seizure threshold should be undertaken only with extreme caution (see WARNINGS).

Physiological changes resulting from smoking cessation itself, with or without treatment with ZYBAN, may alter the pharmacokinetics of some concomitant medications, which may require dosage adjustment.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Lifetime carcinogenicity studies were performed in rats and mice at doses up to 300 and 150 mg/kg per day, respectively. These doses are approximately ten and two times the maximum recommended human dose (MRHD), respectively, on a mg/m^2 basis. In the rat study, there was an increase in nodular proliferative lesions of the liver at doses of 100 to 300 mg/kg per day (approximately three to ten times the MRHD on a mg/m^2 basis); lower doses were not tested. The question of whether or not such lesions may be precursors of neoplasms of the liver is currently unresolved. Similar liver lesions were not seen in the mouse study, and no increase in malignant tumors of the liver and other organs was seen in either study.

Bupropion produced a positive response (two to three times control mutation rate) in two of five strains in the Ames bacterial mutagenicity test and an increase in chromosomal aberrations in one of three in vivo rat bone marrow cytogenic studies.

A fertility study in rats at doses up to 300 mg/kg revealed no evidence of impaired fertility.

Pregnancy: ***Teratogenic Effects: Pregnancy Category B:*** Teratology studies have been performed at doses up to 450 mg/kg in rats (approximately 14 times the MRHD on a mg/m^2 basis), and at doses up to 150 mg/kg in rabbits (approximately 10 times the MRHD on a mg/m^2 basis). There is no evidence of impaired fertility or harm to the fetus due to bupropion. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies not always predictive of human response, this drug should be during pregnancy only if clearly needed. Pregnant smokers shoul encouraged to attempt cessation using educational and behav interventions before pharmacological approaches are used.

Labor and Delivery: The effect of ZYBAN™ on labor and delive humans is unknown.

Nursing Mothers: Bupropion and its metabolites are secreted in hu milk. Because of the potential for serious adverse reactions in nur infants from ZYBAN, a decision should be made whether to discont nursing or to discontinue the drug, taking into account the importanc the drug to the mother.

Pediatric Use: Clinical trials with ZYBAN did not include individ under the age of 18. Therefore, the safety and efficacy in a pedia smoking population have not been established. The immediate-rele formulation of bupropion was studied in 104 pediatric patients (range, 6 to 16) in clinical trials of the drug for other indications. Altho generally well tolerated, the limited exposure is insufficient to assess safety of bupropion in pediatric patients.

Use in the Elderly: In general, older patients are known to metabo drugs more slowly and to be more sensitive to the side effects of dru A single-dose pharmacokinetic study demonstrated that the disposit of bupropion and its metabolites in elderly subjects was similar to tha younger subjects (see CLINICAL PHARMACOLOGY section of prescribing information). Of the approximately 5,600 patients v participated in clinical trials with bupropion sustained-release tabl (depression and smoking cessation studies), 303 were 60 to 69 years and 88 were 70 years of age or older. The experience with patients years of age or older was similar to that in younger patients.

ADVERSE REACTIONS: (see also WARNINGS and PRECAUTIONS)

The information included under ADVERSE REACTIONS is based primarily data from the dose-response trial and the comparative trial that evalua ZYBAN for smoking cessation (see CLINICAL TRIALS section of full prescrib information). Information on additional adverse events associated with t sustained-release formulation of bupropion in depression trials, as well as t immediate-release formulation of bupropion, is included in a separate secti (see Other Events Observed During the Clinical Development a Postmarketing Experience of Bupropion).

Adverse Events Associated With the Discontinuation of Treatme Adverse events were sufficiently troublesome to cause discontinuation treatment in 8% of the 706 patients treated with ZYBAN and 5% of the 3 patients treated with placebo. The more common events leading discontinuation of treatment with ZYBAN included nervous system disturbanc (3.4%), primarily tremors, and skin disorders (2.4%), primarily rashes.

Incidence of Commonly Observed Adverse Events: The most commo observed adverse events consistently associated with the use of ZYBA were dry mouth and insomnia. The most commonly observed advers events were defined as those that consistently occurred at a rate of fi percentage points greater than that for placebo across clinical studies.

Dose Dependency of Adverse Events: The incidence of dry mouth ar insomnia may be related to the dose of ZYBAN. The occurrence of thes adverse events may be minimized by reducing the dose of ZYBAN. addition, insomnia may be minimized by avoiding bedtime doses.

Adverse Events Occurring at an Incidence of 1% or More Amon Patients Treated With ZYBAN: Table 1 enumerates selected treatmen emergent adverse events from the dose-response trial that occurred a an incidence of 1% or more and were more common in patients treate with ZYBAN compared to those treated with placebo. Table 2 enumerate selected treatment-emergent adverse events from the comparative tria that occurred at an incidence of 1% or more and were more common i patients treated with ZYBAN, NTS, or the combination of ZYBAN and NT compared to those treated with placebo. Reported adverse events wer classified using a COSTART-based dictionary.

Table 1

Treatment-Emergent Adverse Event Incidence in the Dose-Response Trial*

Body System/ Adverse Experience	ZYBAN™ 100 to 300 mg/day (n = 461) %	Placebo (n = 150) %
Body (General)		
Neck pain	2	<1
Allergic reaction	1	0
Cardiovascular		
Hot flashes	1	0
Hypertension	1	<1
Digestive		
Dry mouth	11	5
Increased appetite	2	<1
Anorexia	1	<1
Musculoskeletal		
Arthralgia	4	3
Myalgia	2	1
Nervous system		
Insomnia	31	21
Dizziness	8	7
Tremor	2	1
Somnolence	2	1
Thinking abnormality	1	0
Respiratory		
Bronchitis	2	0
Skin		
Pruritus	3	<1
Rash	3	<1
Dry skin	2	0
Urticaria	1	0
Special Senses		
Taste perversion	2	<1

*Selected adverse events with an incidence of at least 1% of patients treated with ZYBAN and more frequent than in the placebo group.

NEW AID TO
SMOKING
CESSATION
TREATMENT

FINALLY, A NON-NICOTINE TABLET THOUGHT TO WORK ON THE BIOLOGY OF NICOTINE ADDICTION

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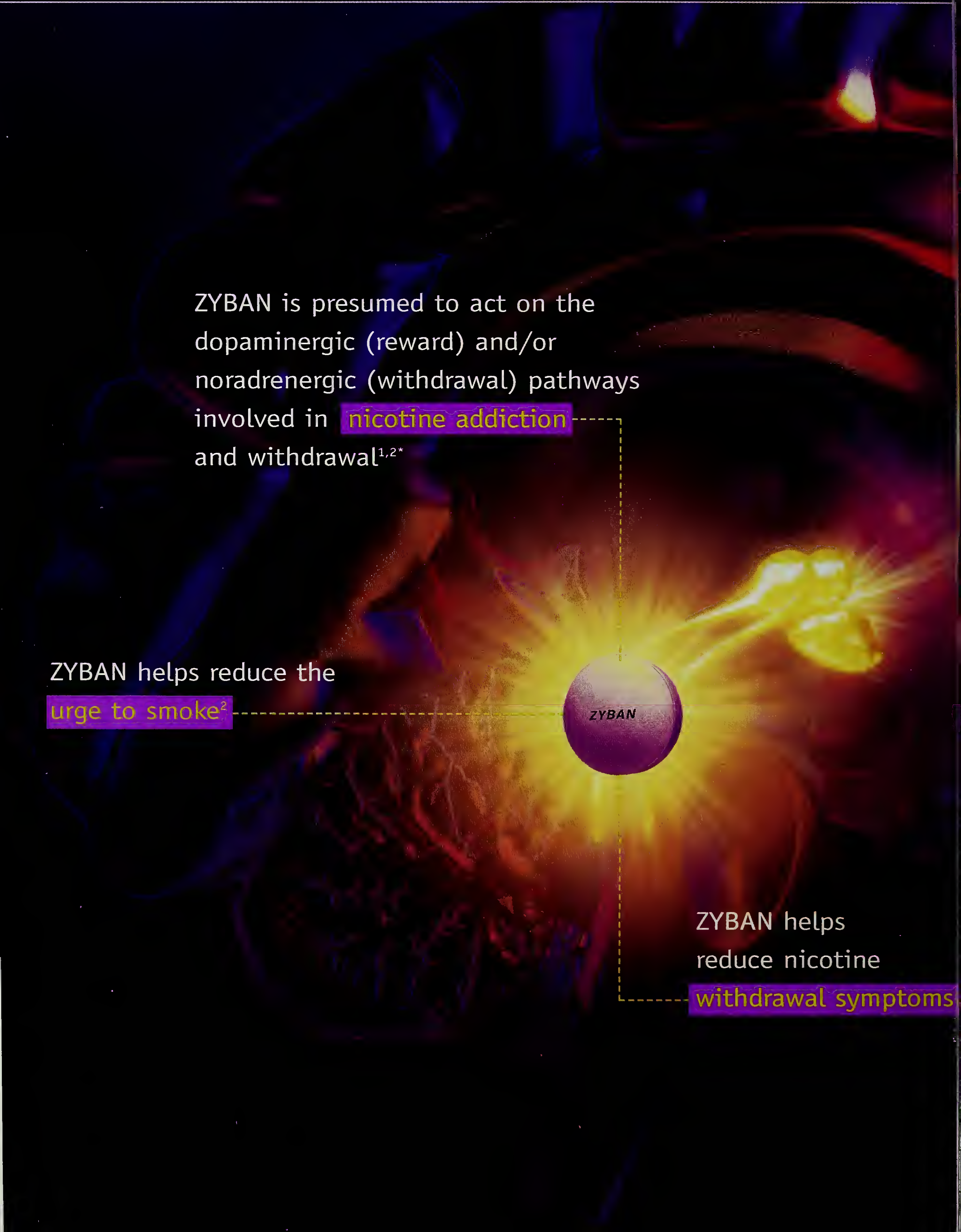


ZYBAN is presumed to act on the dopaminergic (reward) and/or noradrenergic (withdrawal) pathways involved in nicotine addiction and withdrawal[1,2*]

ZYBAN helps reduce the urge to smoke[2]

ZYBAN helps reduce nicotine withdrawal symptoms

RGE TO SMOKE

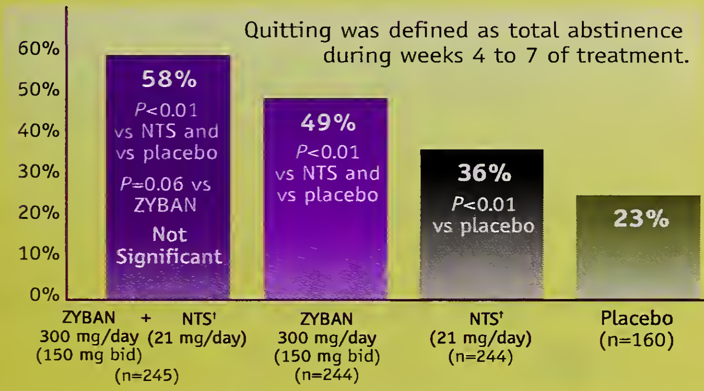
NEW

ZYBAN™

bupropion HCl sustained-release tablets 150 mg

NEUROCHEMISTRY. NOT NICOTINE.

Significantly higher 4-week quit rates than nicotine patch† in a 9-week‡ comparative trial[2]



Data are from a multicenter, double-blind, placebo-controlled, parallel, randomized trial. All patients were administered either an active or a placebo tablet and wore either an active or a placebo patch. Patients received brief (5-10 minutes) individual smoking cessation and relapse prevention counseling.

† Habitrol® (nicotine transdermal system) (NTS) 21 mg/day. Ciba-Geigy Corp.

‡ NTS therapy was initiated at the target quit day (days 8 to 14) and tapered at week 8 (14 mg/day) and at week 9 (7 mg/day). ZYBAN was not tapered.

Quit rates in clinical trials are influenced by the population selected. Quit rates in an unselected population may be lower than the above rates.

First-line therapy as an aid to smoking cessation treatment

- ZYBAN helps reduce nicotine withdrawal symptoms and the urge to smoke, presumably through neurochemical pathways.[2]
- Patients start ZYBAN 1 to 2 weeks before their target "quit day"... unlike nicotine replacement therapy.
- For the remainder of 7 to 12 weeks of therapy, ZYBAN provides pharmacological treatment along with individualized patient support, the ZYBAN Advantage Plan™.
- This plan should be part of a comprehensive smoking cessation treatment program to help your patients' chances of success.

Adverse event profile: Most common adverse events were dry mouth and insomnia.

*Studies were conducted in animal models. The mechanism of action is unknown.

Please consult brief summary of Prescribing Information on last page.

NEW

ZYBAN™

bupropion HCl sustained-release tablets 150 mg

NEUROCHEMISTRY. NOT NICOTINE.

The ZYBAN Advantage Plan™

Individual counseling and support with the only non-nicotine medication for smoking cessation

- Easy enrollment by patients
- Designed to address an individual's smoking "triggers"

Encourage your patients to enroll in the ZYBAN Advantage Plan. Advise them of the importance of participating in behavioral interventions and counseling as part of their quit attempt.

Usage

- ZYBAN is indicated as an aid to smoking cessation treatment in smokers 18 years of age and older.

How to conveniently prescribe ZYBAN

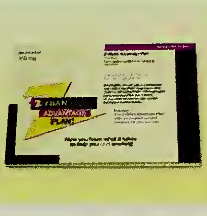
Dosing should begin at 150 mg/day for the first 3 days.

Increase dosage to the recommended and maximum 300 mg/day (150 mg bid) for most patients for 7 to 12 weeks.* Allow at least 8 hours between successive doses.

MONTH 1

RX OPTION 1

Dispense ZYBAN Sample Pack:
Contains first 3 days of therapy and the ZYBAN Advantage Plan™ (Available only from your Glaxo Wellcome representative)



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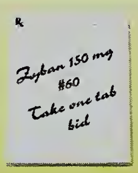
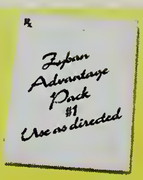


℞
Zyban 150 mg
#60
Take one tab
bid

OR

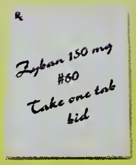
RX OPTION 2

Write Rx for ZYBAN Advantage Pack™:
Contains 1 month of therapy and the ZYBAN Advantage Plan (Available at pharmacies)



℞
Zyban
Advantage
Pack
#1
Use as directed

MONTHS 2 TO 3



℞
Zyban 150 mg
#60
Take one tab
bid

Write Rx
for ZYBAN
Tablets
150 mg bid
#60

*Clinical data are not available on the long-term use (>12 weeks) of bupropion for smoking cessation.

ZYBAN is contraindicated in patients with a seizure disorder or with a current or prior diagnosis of bulimia or anorexia nervosa. The concurrent administration of ZYBAN Tablets and an MAO inhibitor is contraindicated.

ZYBAN contains the same active ingredient found in WELLBUTRIN® and WELLBUTRIN SR® used to treat depression, and should not be used in combination with WELLBUTRIN, WELLBUTRIN SR, or any other medications that contain bupropion.

The use of bupropion is associated with a dose-dependent risk of seizures. Therefore, *clinicians should not prescribe doses over 300 mg/day for smoking cessation.* The risk of seizures is also related to patient factors, clinical situation, and concurrent medications, which must be considered in selection of patients for therapy with ZYBAN.

Please consult brief summary of Prescribing Information on next page.

Connecticut Medicine

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ntific:

Hussain, *Mag enkranz,* *Victo C. Rowe*	131	**Pre-discharge Outcomes of 22–27 Weeks Gestational Age Infants Born at Tertiary Care Centers in Connecticut: Implications for Perinatal Management**
I I. Goldie	139	**Teaching Care of Terminally Ill Patients: A Primary Care Perspective**
Andr Banever	143	**Frequency of Breast Biopsy and Breast Cancer Diagnosis in Central Connecticut—Trends From 1993 to 1997**
Coolican *Swanson*	149	**Primary Health-care Physicians: Vital Roles in Organ and Tissue Donation**
		Epitomes of Progress
E. Wilson	155	**Important Advances in Clinical Medicine—General Surgery**
		Drug Information Update: Hartford Hospital
icherson, *Pau intiliani,* *ghtingale*	165	**Formulary Review of the Carbapenems: Comparison of Imipenem/Cilastatin and Meropenem**

rticles:

l I. Robin	171	**Address for White Coat Ceremony: New York Medical College Convocation**

guest editorial:

Patrick P. Coll	174	**Assistance with Suicide**

departments:

		Fifty Years Ago
	175	**Medical Practice Group**
		The President's Page
Stanley J. Keating, Jr.	177	**Evaluation and Management Coding**
		Reflections on Medicine
Robert U. Massey	179	**Hermann Helmholtz: From Army Surgeon to Physicist**
		Medical News Capsules
Timothy B. Norbeck	181	**This Month's Reading in Review**
		Letters to the Editor
John M. Keggi	183	**In Response to Connecticut College of Emergency Physicians' Abstract by Drs. Daly and Reiser**
Raymond Yesner	183	**In Response to "Outbreak of Staphylococcal Food Poisoning Associated with Precooked Ham—Florida, 1997"**
Charles W. Needham	184	**Remembering Wilder Penfield**
Lamson Blaney	184	**Professional Vacuum**
Philip I. Kotch	185	**The Misnomer "Physician Assisted Living"**
Edward Volpintesta	185	**Is There a Place for Hospitalists in Health-care Reform?**
		From the Executive Director's Office
CSMS	187	**Call**

general:

	188	**In Memoriam**
	190	**CSMS Physician Placement Service**

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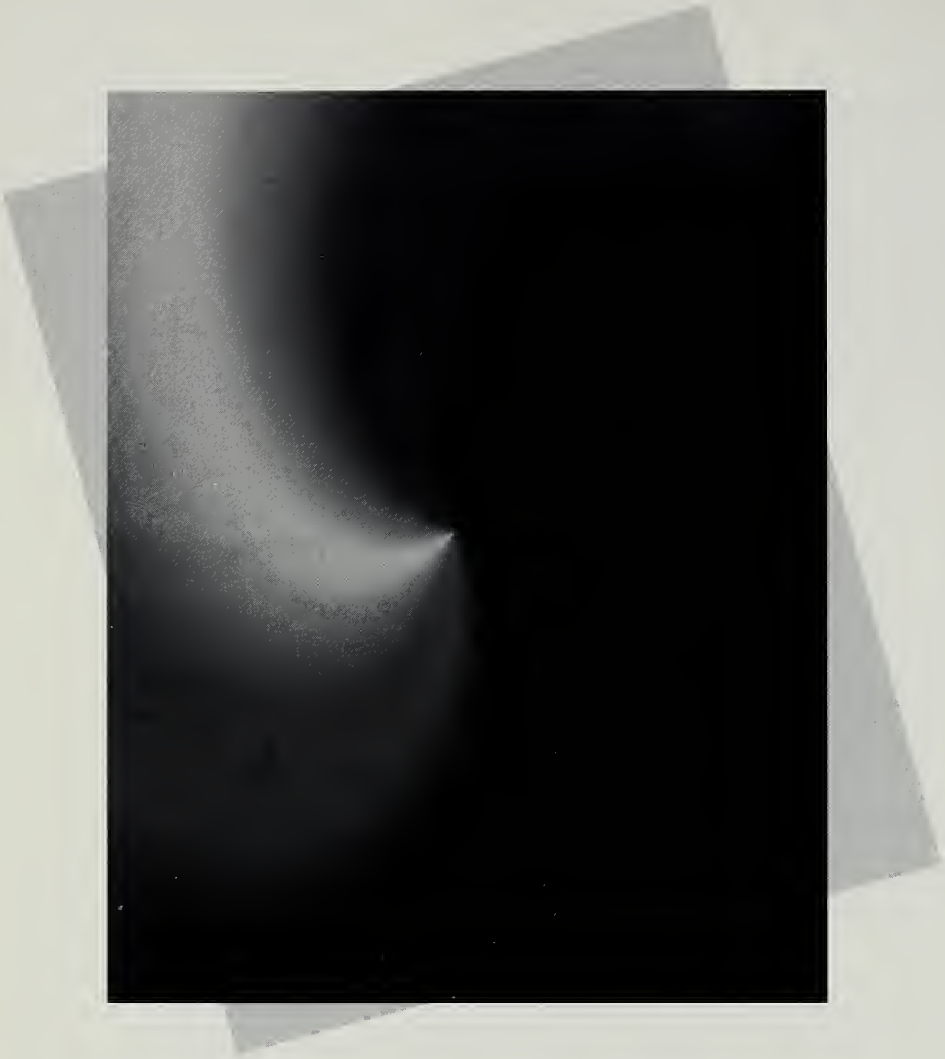

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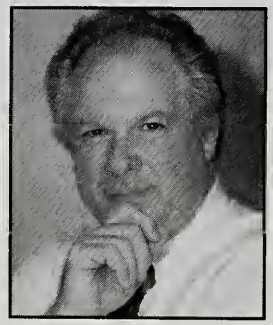

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Pre-discharge Outcomes of 22–27 Weeks Gestational Age Infants Born at Tertiary Care Centers in Connecticut: Implications for Perinatal Management

NAVEED HUSSAIN, M.B.B.S., MAGDY GALAL, M.D.,
RICHARD A. EHRENKRANZ, M.D., VICTOR C. HERSON, M.D.,
AND JONELLE C. ROWE, M.D.

ABSTRACT—There is a lack of regional data on survival and morbidity of extremely premature infants born and resuscitated at tertiary care centers. This study analyzes such data from three tertiary-care perinatal centers in Connecticut and provides a paradigm for its use in developing guidelines for evidence-based ethical considerations in infants at the threshold of viability. Outcomes of inborn infants 22 to 27 weeks gestation (based on obstetric estimates) who were actively resuscitated at three regional perinatal tertiary-care centers (representing 80% of such infants from Connecticut) were studied retrospectively. Survival and cumulative major morbidities at discharge, stratified by gestational age, were analyzed. Of the 405 infants studied, 278 (69%) survived to discharge. There were no survivors beyond three days at 22 weeks gestational age. Unfavorable outcome defined as death or major morbidity (≥ grade 2 intraventricular hemorrhage, periventricular leukomalacia, ≥ Stage 3 retinopathy of prematurity, necrotizing enterocolitis ≥ Stage 2, and severe bronchopulmonary dysplasia at 36 weeks postmenstrual age.) was seen in > 85% of 23 and 24 week gestation infants. At 25 weeks ≃ 30% of infants were discharged without an unfavorable outcome. At 26 and 27 weeks gestation 43% and 61% respectively escaped unfavorable outcomes with > 85% rates of survival. Current regional data such as these would help in developing guidelines for the perinatal management of premature infants at the threshold of viability.

Introduction

ADVANCES in technology and a better understanding of fetal and neonatal physiology has made it possible to sustain life in extremely immature infants. Mortality and morbidity data available from various sources have failed to distinguish infants that were resuscitated *vs* those that received only compassionate care.[1] Therefore their data are liable to misrepresent the mortality risks especially in the most immature of the infants and promulgate a self-fulfilling prophecy where the most immature are not resuscitated and therefore do not survive.[2] To determine true mortality and morbidity risks we need to answer the following question: given perinatal care at a tertiary care center and neonatal resuscitation at birth, what are the chances of survival and morbidity of extremely low birth weight, gestationally immature infants?

Abbreviations Used in Text

BPD = bronchopulmonary dysplasia
IND = investigational new drug
IVH = intraventricular hemorrage
NEC = necrotizing enterocolitis
PVL = periventricular leukomalacia
ROP = retinopathy of prematurity

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Such data from a specific region may reflect the best case scenario for that area. These medical data need to be processed in the light of parental needs and expectations incorporating the societal judgment of cost relative to value in order to help develop evidence-based ethical guidelines for decision making for extremely immature infants at the threshold of viability. This study from three major Connecticut regional tertiary-care neonatal units is such an attempt.

Patients and Methods

Hospitals.—Outcomes from three major tertiary-care perinatal centers in Connecticut were studied: the University of Connecticut John Dempsey Hospital in Farmington, Hartford Hospital, and now the Connecticut Children's Medical Center in Hartford, and the Yale Children's Hospital in New Haven. These account for about 80% of all inborn high-risk premature deliveries in the state of Connecticut.

Study Period.—Infants included were those born at 22 to 27 weeks completed gestational age by dates from 1 August 1989 to 30 July 1993 at John Dempsey Hospital (n = 188) and Hartford Hospital (n = 107), and from 1 January 1991 to 30 July 1993 at Yale Children's Hospital (n = 110). Surfactant replacement therapy was available under similar protocols for management of respiratory distress syndrome (RDS) during this time period at all the units.

Data Collection.—Data were collected retrospectively from computerized data bases or review of labor and delivery log-books at all the centers. Mode of delivery, gender, maternal race, birth weight, gestational age, oxygen requirement at 36 weeks postmenstrual age, grades of intraventricular hemorrhage (IVH), periventricular leukomalacia (PVL), stages of retinopathy of prematurity (ROP), stages of necrotizing enterocolitis (NEC), and length of stay in the neonatal unit before death or discharge were collected and documented for each infant.

Inclusion and exclusion criteria.—Infants were included if gestational ages were between 22 to 27 completed weeks by antenatal obstetric estimates, peripartum care of the mother and delivery were at a high-risk tertiary-care center, and active resuscitation of the infant was done in the delivery room, including positive pressure ventilation. Infants were excluded if they were stillborn, were live born but not actively resuscitated, or had severe life threatening congenital anomalies.

Management policies.—In general, the management of fetuses and infants at these gestational ages was based on consultation among the obstetric and neonatal teams and discussions with families.

Antenatal fetal monitoring and fetal indications for cesarean-section were considered at ≥ 23-weeks gestational age. After birth, neonatal intensive care was not instituted for 22-weeks gestational age infants at Hartford Hospital and Yale Children's Hospital whereas at John Dempsey Hospital, eight such infants were actively resuscitated and treated. For infants born at 23-weeks gestational age and beyond, all three centers provided active resuscitation for infants in the delivery room based on the evaluation of a neonatologist or an experienced neonatal fellow. Surfactant was given under the treatment investigational new drug until June 1991, and later was given as per physician discretion and the approach was uniform between the three centers.

Gestational age assessment.—The estimation of gestational age was based on the date of the last menstrual period of the mother, clinical evaluation of early uterine size, ultrasonography of the fetus early in gestation, and/or at admission. The majority (70%) had early gestation ultrasound. Postnatal assessment of maturity was not relied on in this study because of its known inaccuracies in extreme prematurity.[3]

Survival.—The end point of the study for each infant was death or discharge from the neonatal unit. Survival rates at discharge are reported.

Morbidity.—Morbidity among survivors was noted during the stay in the neonatal unit. Respiratory morbidity studied was the incidence of bronchopulmonary dysplasia (BPD) as defined by Bancalari.[4] Severe BPD, defined as the infants with BPD who had persistent oxygen requirement at >36-weeks postmenstrual age, was considered a major morbidity. Total days on oxygen therapy were also noted.

Nonrespiratory morbidity.—Cranial ultrasonography was performed in all infants at least three times : one to three days after birth, at five to 10 days after birth, and before discharge. IVH was graded (1–4) by the experienced ultrasonographers using the Papile system.[5] PVL was defined as intracerebral cyst formation observed at any time. Ophthalmologic evaluation was performed periodically by pediatric ophthalmologists starting at about six weeks of age with follow-up as required. ROP was staged based on the international classification.[6] NEC was considered significant if there were definite clinical and radiological signs corresponding to Bell's classification stages 2 or 3.[7]

Major morbidities.—These were (a) the incidence of ≥ grade 2 IVH or any degree of PVL, (b) ≥ Stage 3 ROP, (c) NEC ≥ Stage 2, and (d) severe BPD at 36-weeks postmenstrual age. Infants who died and those who suffered from one or more major morbidities prior to discharge were considered to have unfavorable outcomes.

In addition, the length of stay in the tertiary-care centers was recorded. Some infants were discharged home and some to other hospitals for growth or monitoring.

Statistics.—Continuous variables were analyzed by unpaired Student's *t* tests. Dichotomous variables were analyzed by χ^2 test. Data are expressed as mean ± 1 SD where applicable. *P* value of ≤ 0.05 was considered significant.

Results

Distribution of patient populations.—A total of 405 infants who were 22 to 27 weeks gestation at birth were included in the study. Overall survival rates of these infants at the three centers were comparable (73% John Dempsey Hospital, 66% Hartford Hospital, and 62% Yale Children's Hospital).

Demographic characteristics. (Table 1).—The mean birth weights of these infants by gestational age were consistent with regional data collected by the State Health Department in the same era.[8] Fifty-three percent of study infants were male and 63% were born to white mothers. This is comparable to Connecticut population data.[8]

Survival to discharge.—Survival to discharge is shown in Table 2 stratified by completed gestational age week at birth and by gender.

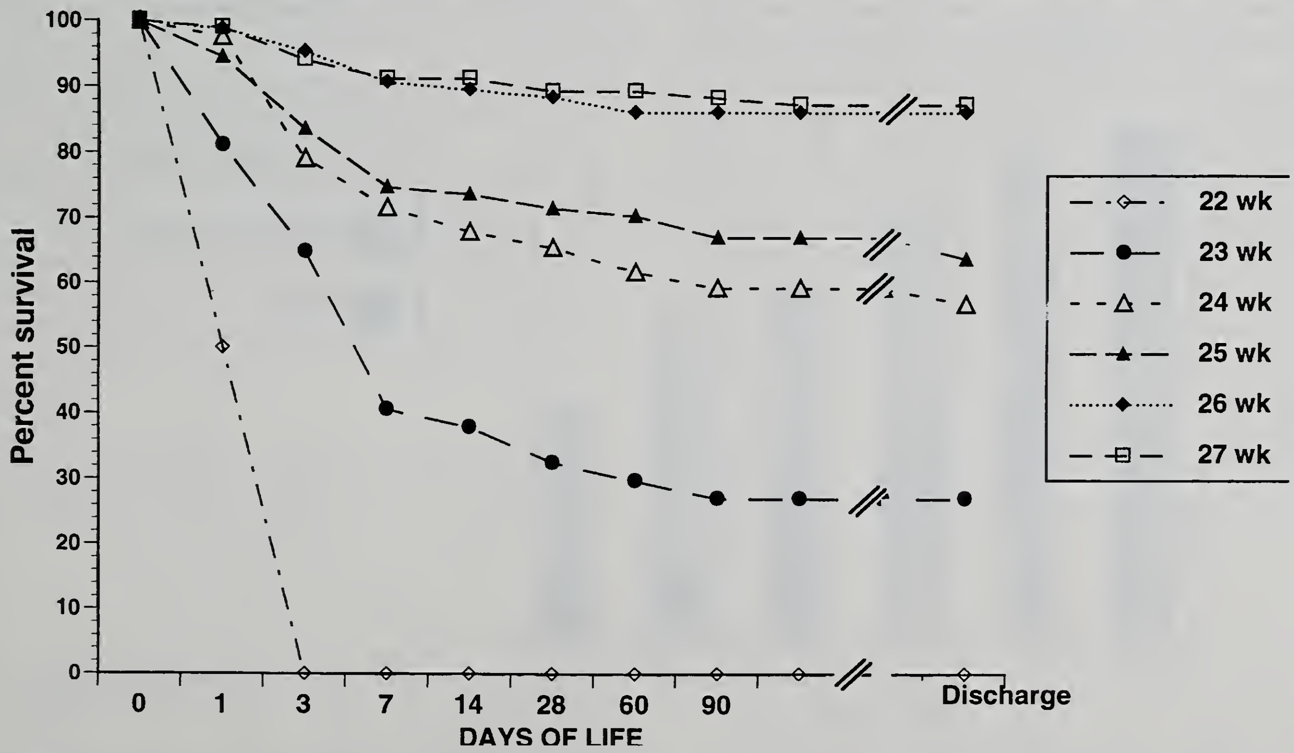
Fig. 1 shows survival trends over time, stratified by gestational age. Most of the deaths occurred within the first three to seven days and if an infant survived beyond that time the chances for survival to discharge were very high.

Morbidity in survivors.—Using the Bancalari criteria,[4] 80% of infants born at ≤ 27 weeks gestational age had BPD. Severe BPD (requirement for supplemental oxygen persisting beyond 36 weeks postmenstrual age) was seen in about half of them. The respiratory morbidity in survivors, stratified by gestational age, is listed in Table 3.

Overall survival for this population was 69% (278/405). These survivors were stratified by gestational age and their incidence of major morbidity shown in Table 4. Percent survivors without major morbidity were determined for each gestational age.

Fig. 2 represents a composite of overall outcome at discharge in each gestational age category. Of 100% infants resuscitated at each gestational age week, the percent of infants who died, and the percent who survived with or without major morbidity are depicted. The percent of infants with unfavorable outcomes are the sum of the percent who died and the percent survived with major morbidity.

Comparison of perinatal variables between infants with or without unfavorable outcome.—We compared the perinatal variables of gender, maternal race, birth weight, gestational age at birth, Apgar score ≤ 3 at one minute, Apgar score ≤ 5 at five minutes, and mode of delivery between the groups of infants who suffered unfavorable outcome and those who did not. Results of the comparison are shown in Table 5.



Among infants who were resuscitated at birth, survival was studied from the time of birth to discharge from the tertiary-care neonatal unit. Percent survival at each time point was plotted for each completed week of gestational age at birth.

Figure 1.—Percent infants surviving from birth to discharge.

Discussion

This study represents the first large regional report of survival and morbidity of extremely premature infants who were delivered in high-risk perinatal centers and given neonatal resuscitation, including positive pressure ventilation. Most previous studies of survival and morbidity have not differentiated between infants that were resuscitated and those that were not, making it difficult to develop guidelines on which perinatal decisions may be based.

Gestational age maturity and birth weight are probably the most important factors determining survival. Prior to the birth of the infant, information on gestational age is more readily available to the obstetrician, and based on this information consultation with the neonatologist is initiated. Therefore information on gestational age-based outcomes plays an important part in decision making prior to birth and influences perinatal management. The current study provides data on gestational age-specific survival and short term morbidity in extremely immature infants.

Survival.—At ≤ 21-weeks gestational age, the biologic immaturity of the lung,[9] which has not yet gone through the canalicular phase of development, precludes adequate gas exchange with any form of currently available technology. Most neonatologists consider these infants to be previable.[10]

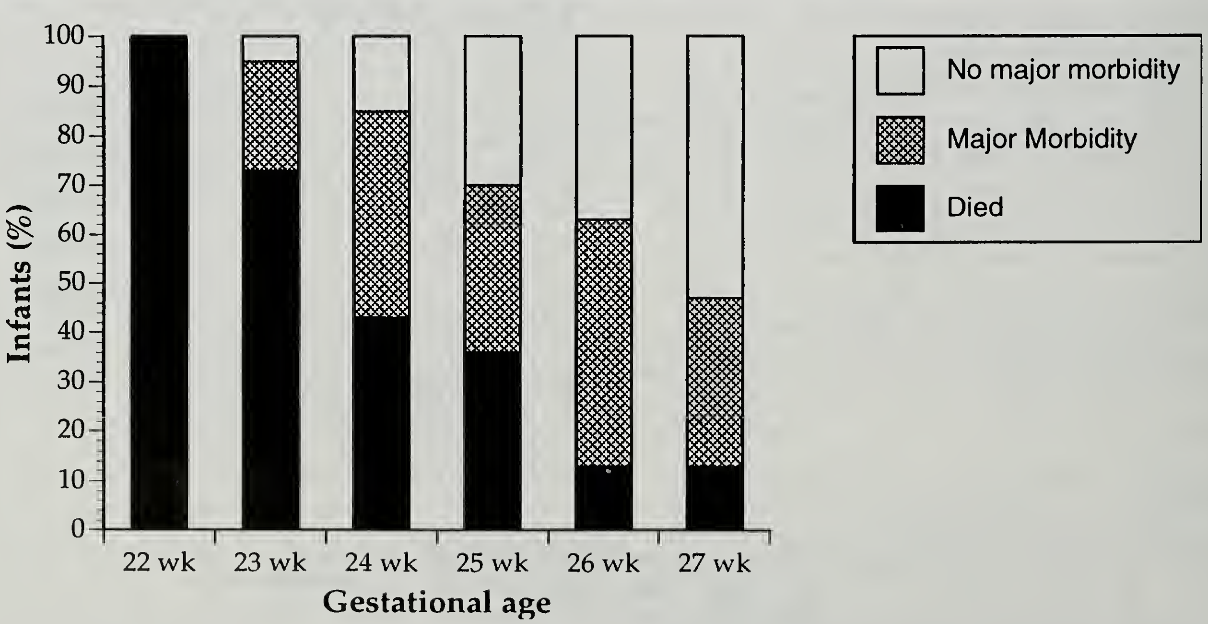
Most earlier reports have not focused on the 22-weeks gestational age infant. To our knowledge, there has been only one series from Japan of survival at this gestational age.[2] Only one center in this study (John Dempsey Hospital) attempted resuscitation at this gestational age. From our observation of eight infants thus resuscitated we report no survivors beyond seven days. This is similar to the observations on three infants made by Allen et al[1] and the findings of the Committee on Fetal Extrauterine Survivability of the New York State Task Force on Life and the Law.[10]

At 23 weeks gestational age, survival has been well documented.[1,11-15] However, when the overall outcome was considered, in our study, 95% of infants born at this gestational age had an unfavorable outcome (either died or had major morbidities) at the time of discharge. This is again very similar to the findings of Allen et al,[1] who reported a 93% incidence of adverse outcome (not including respiratory morbidity or NEC) in their study.

At 24 weeks gestational age, there is a more tangible improvement in survival rates (57%); however the risks of dying or suffering from a major morbidity before discharge are still considerable (~85% unfavorable outcome). Allen's study[1] found an adverse outcome of 67% without including respiratory morbidity or NEC.

At 25 and 26 weeks gestational age, there is a distinct change in outcome, with the majority of infants being survivors (64% and 87% respectively). However, there is still a considerable price to pay in pain, suffering, and morbidity, but the chances for survival without major morbidity exceed 30%.

At 27 weeks gestational age, survival remains 87%, the chances for escaping any major morbidity are now greater than 50%.



Of the infants resuscitated at birth, percent who died before hospital discharge and percent with and without major morbidity during hospital stay were plotted. Major hospital morbidity included grade 2 IVH, any degree of PVL, stage 3 ROP, stage 2 NEC, or severe BPD at 36 weeks postmenstrual age.

Figure 2.—Overall outcomes at discharge in extremely premature infants (22 to 27 weeks gestational age).

Table 1.—Patient Characteristics

Gestational age (weeks)	**22**	**23**	**24**	**25**	**26**	**27**
No. of infants	8	37	81	91	86	102
Birth-weight mean ± SD (g)	501 ± 113	580 ± 79	638 ± 107	733 ± 121	855 ± 144	994 ± 162
Percentage males	75%	62%	47%	56%	56%	52%
Percentage white	50%	60%	53%	47%	58%	52%

Prolonging death.—Concerns have been raised about prolonging the process of dying in these extremely low birth infants.[1] The data shown here suggest that most infants who die do so within the first three to seven days of life even at 22 to 24 weeks. It is reassuring that in the vast majority of infants who are treated, there is no prolongation of an inevitable death.

Morbidity.—Morbidities that are designated major morbidities for this study are different from those used in the reports of Allen and Lefebvre, in that severe BPD and stage 2 and 3 NEC are included. Severe BPD at 36 weeks postmenstrual age was considered a major morbidity because these infants have a significantly decreased respiratory reserve.[16] Stages 2 or 3 of NEC, have an immediate effect on an infant's growth and nutrition which in turn has consequences for future growth.[17] The consequences for IVH/PVL[18] and ROP[19] are obvious in their effect on neurodevelopmental outcomes. All these were chosen for their known consequences for immediate care of the infant in the hospital as well as their effect on the level of care and support that the infant might need after being discharged home. They all have serious effects on the life experience of the infant and the family.

There are no prominent differences in morbidity rates between this study and the National Institute of Child Health and Human Development report[12] or the study by Lefebvre,[14] but some of the differences in specific morbidity, especially the low incidence of IVH, PVL, and ROP in our report, may be attributed to regional differences in the populations.

We found no statistical difference in race or gender in the study population of infants who suffered from an unfavorable outcome (death or major morbidity) and those who did not. This is different from other reports.[12,20] This may be due to the relatively small number of infants in the 22 to 25 week gestational age groups in this study. Lower birth-weight, Apgar scores of ≤ 3 at one minute, and ≤ 5 at five minutes were significantly more frequent ($P < 0.0001$) in those with unfavorable outcome; whereas the mode of delivery, whether vaginal or cesarean section, was not significant.

So, what should be done when faced with an impending birth of an extremely premature infant? The Canadian consensus statement based on available data until 1993, recommended that "treatment of all infants with a gestational age of 22 to 26 weeks should be tailored to the infant and the family and should involve fully informed parents."[20] The combined statement on "perinatal care at the threshold of viability,"[21] from the American Academy of Pediatrics and the American College of Obstetrics and Gynecology highlighted the need for current and regional data but refrained from making any recommendations.

We propose that the dilemma of management of birth of an infant of extremely low gestational age be approached in the evidence-based ethics paradigm as proposed by Tyson who classified care categories based on medical, parental, and societal consensus, viz., (i) unreasonable care, which ought not to be offered to the infant; (ii) investigational care, offered only in research-funded investigational centers to the infant with full parental involvement in assessing and understanding the burden/benefit ratios; (iii) optional care, offered in most centers with parental involvement but with their right to decline care; and (iv) mandatory care, where parents do not have the right to decline care.[22] In this paradigm, we believe, infants born at ≥ 21 weeks gestational age could be placed in the unreasonable care category because survival has not been possible at this early gestational age. Infants born at

Table 2.—Survival by Gestational Age and Gender

Gestational age (weeks)	**22**		**23**		**24**		**25**		**26**		**27**	
Gender	M	F	M	F	M	F	M	F	M	F	M	F
Live-born (n)	6	2	23	14	38	43	51	40	45	41	53	49
Discharged (%)	0(0%)	0(0%)	9(39%)	1(7%)	16(42%)	30(60%)	36(61%)	22(55%)	38(84%)	37(90%)	9(83%)	4(92%)
Percentage survival	0%		27%		57%		64%		87%		87%	

Table 3.—Respiratory Morbidity in Survivors

Gestational age (wk)	23	24	25	26	27	23–27
Survivors (n)	10	46	58	75	89	278
Hospital days (mean ± SD)	121 ± 22	103 ± 36	95 ± 31	98 ± 40	77± 38	92 ± 37
Ventilator days (mean ± SD)	42 ± 24	37 ± 20	26 ± 17	27 ± 22	12 ± 15	24 ± 21
Days in oxygen (mean ± SD)	88 ± 43	86 ± 49	57 ± 36	68 ± 49	43 ± 38	62 ± 46
BPD at 28 days (%)	9 (90%)	40 (87%)	46 (79%)	63 (84%)	50 (56%)	208 (75%)
Severe BPD at 36 weeks corrected age (%)	5 (50%)	27 (59%)	19 (33%)	33 (44%)	22 (25%)	106 (38%)

22 weeks gestational age could fall into the category of investigational care and special centers might be identified in the country where this may be carried out. For infants born at 23 and 24 weeks gestational age, given the very high mortality rates, the very poor chances for survival without a major morbidity, and the long length of suffering in the neonatal intensive care unit (average length of stay >100 day), treatment may be considered optional, with parents reserving the right to decline life support for their infant. The high levels of uncertainty and the high burden of pain and suffering for the infant and the family make for difficult decisions to treat or not to treat at these gestational ages. Detailed discussions held with parents should be done before undertaking resuscitative efforts under these circumstances. In emergency situations with no time for such discussions or where data are inadequate to make reasonable decisions, resuscitation may be initiated with periodic review of the clinical course of the infant with the family. It is very important to bear in mind that, except with assisted fertilization, an accurate assessment of gestational age may be difficult and a reasonable benefit of doubt may be given to accommodate the parents' wishes and expectations.

For infants born at 25 weeks and beyond, treatment might be considered mandatory unless there are other extenuating circumstances besides prematurity which would compromise survival. This paradigm takes into consideration current regional medical data along with informed input from parents, and examines both in the context of societal judgment of cost relative to value.

In this study, we have analyzed current regional data on survival and predischarge morbidity of extremely immature infants who were delivered at tertiary centers and provided neonatal resuscitation. We have also proposed using such data in a paradigm of evidence-based ethics to help in decision-making at the threshold of viability. However, it should be noted that the data in our study, being based on a single region and lacking information on long-term morbidity, would not be sufficient to draw definitive guidelines. What we propose are suggestions for further study. We hope that future studies from more than one region will provide sufficient survival and morbidity data from which a consensus statement could be developed to guide parents and health-care providers in providing optimal care for premature infants and their families.

Table 4.—Major Morbidity in Survivors

Gestational age (wk)	22	23	24	25	26	27	23–27
Number resuscitated (n)	8	37	81	91	86	102	405
Survival to discharge (n)	0	10	46	58	75	89	278
Grade 2 IVH / PVL (n)	0	1	7	9	14	13	44 (16%)
Stage 3 ROP (n)	0	2	12	10	8	4	36 (13%)
Stage 2 NEC (n)	0	1	4	4	6	4	19 (17%)
Severe BPD at 36 weeks corrected (n)	0	5	27	19	33	22	106 (38%)
No major morbidity (n)	0	2	12	27	32	54	127
Percentage of survivors w/out major morbidity	0%	20%	27%	47%	43%	61%	46%

Table 5.—Comparison of Perinatal Variables and Outcome

	No Major Morbidity (n = 127)	**Died or Major Morbidity (UO) (n = 278)**	***P* Value**
Gestational age (wk) mean ± SD	25.9 ± 1.16	24.9 ± 1.4	<0.0001
Birth weight (gm) mean ± SD	899 ± 177	735 ± 188	<0.0001
Maternal race (hite) %	30%	32%	ns
Gender (male) %	47%	56%	ns
Apgar ≤ 3 @ one minute %	26%	58%	<0.0001
Apgar ≤ 5 @ five minute %	14%	40%	<0.0001
Delivery type (vaginal) %	40%	42%	ns

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Teaching Care of Terminally Ill Patients: A Primary Care Perspective

NANCY R. ANGOFF, M.D. AND SUE J. GOLDIE, M.D.

ABSTRACT—Currently there is a great interest in educating medical students in the care of patients with terminal illness. When medical students do encounter patients with terminal illness, it is often in the acute care setting. We have designed a workshop for fourth-year medical students who are working in general medical, family, or pediatrics practices as part of their month-long primary-care clerkship. The emphasis of this workshop is on the care of the terminally ill patient as a natural extension of the continuum of care offered by a primary-care physician. The workshop involves an interactive interview of a patient with a terminal illness by a group of four to eight students and the guidance of an experienced physician facilitator. Four themes are identified as central to the primary care of patients with terminal illness, and emphasis is placed on communication skills and the meaning of language to the dying patient.

Introduction

RECENTLY various professional and educational organizations have become interested in promoting more formalized education of medical students and residents in caring for patients who are dying.[1–3] Concern for the adequacy of medical school curricula addressing this topic and the call for improved formal courses on caring for dying patients and on communication skills with dying patients and their families is not new.[4–9] Even where the issue of death and dying is included in medical school curricula, it is often in the context of courses that focus on relationships with patients who have either already come to terms with their dying, such as those who have chosen hospice care, or those who come to the hospital to die.[10] Frequently the topic is not comprehensively encountered by medical students until precipitated by end-of-life decisions in an intensive care unit or decisions involving "do not resuscitate orders."

Traditionally, and most pronounced in the clinical years of medical school, teaching medical students about the care of patients with terminal illness is displaced to the acute care setting where the students spend most of their time; thus, caring for the dying is kept distinct from general primary-care medicine. With the reform in health-care delivery and the inevitable changes in the way medicine is practiced in the current managed-care era, the primary-care gatekeeper, as in the days of the "old family doctor," has a unique opportunity to come to know patients over time and comprehensively. It is within this long-term relationship that a patient and physician encounter terminal illness and all of the associated decisions. The tertiary-care teaching hospital exists for more focused and specialized problem-solving visits. Sometimes these visits culminate in a patient's death unexpectedly, and sometimes patients with a terminal illness need the specialized care of the hospital; but less and less the hospital is, or should be, the environment that gives shape to the plans for the death of a terminally ill patient.

The care of the dying patient belongs in the continuum of a primary-care relationship. There are many societal forces that support the timeliness and importance of this view. Some of these forces include: the cost effectiveness models of managed care with an emphasis on minimizing

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inpatient care and length of stay; respect for patient choices and autonomy in decision making; public desire for the "good doctor," the physician who pays attention to the whole patient and not just the patient's disease; and the public's fear of suffering or dying alone and unabetted.[11-17] The kind of care that we advocate cannot be provided by strangers who only know the patient in the context of an admission to the hospital. This type of comprehensive care is optimally provided by a primary-care physician who comes to know the patient through a continuum of encounters. It is during these multiple and varied interactions that death may be planned and prepared for, and individual attitudes, beliefs, and choices made known. The ultimate goal is to help the patient maintain control, in contrast to allowing a situation to unfold that is often best characterized as an ultimate loss of control.

Methods

At Yale University School of Medicine, fourth-year students work in a general medical, family, or pediatric practice following patients under the close supervision of a physician-preceptor. During this month-long primary-care clerkship, groups of four to eight students attend two-hour workshops exploring core topics integral to primary care. In one of these workshops students are introduced to the concept of primary care as a continuum wherein the relationship between physician and patient begins in sickness or health, endures acute and chronic illness, and moves back and forth between health-related problems over time, possibly until the patient's death. At any point along this continuum, terminal illness may be identified.

Introduction.—Four themes are identified as central to the primary care of patients with terminal illness: 1) The first theme emphasizes that the work-up, diagnosis, treatment, and place of death can be expanded to a broad spectrum of outpatient settings and services. 2) The second theme focuses on the integral role of patient choices; patients have different cultural backgrounds, religions, social supports, and values all of which need to be considered in decision making. 3) The third theme involves the time a change in the direction of care occurs, from cure-oriented to comfort-oriented. The diagnostic skills and tools used to deliver cure-oriented care are identical to those needed to provide quality palliative care. 4) The final theme perhaps presents the most difficult struggle for a physician. Maintaining hope balanced by realism is difficult but crucial, and demands attention to the patient's spiritual health.[18]

Interactive Interview.—The above themes are presented to the student utilizing interactive discussion and outlined on a worksheet that the students use as a means to facilitate critical observation of the session. They ask questions and explore aspects of the patient's terminal illness in the context of the medical care received. Woven throughout all of the themes is the issue of communication. We ask students to pay attention to how well physicians and patients speak and listen to one another, and there is a section on the worksheet for them to document these observations.

A patient who has a terminal illness attends the workshop and tells her story. It is within the story of the patient that the themes become evident, and it is by becoming part of that story that the students begin to express themselves with dying patients. Howard Brody states, "... an openness to and acceptance of the story that captures the patient's individualized response to an illness episode must be one of the key ingredients of the compassion we seek." [19] In a very real sense the students do become a part of the patient's story. In an open discussion with the patient the students ask questions, often finding themselves caught up in a struggle and debate similar to that with which the patient's own primary-care physician contends. Rather than just commenting on communication skills, the students have to develop their own. To various degrees each story emphasizes one or more of the four themes and the students have the opportunity to place themselves in relationship to the patient in dealing with each theme. For the patient, the session becomes an opportunity to expand a story of illness to include contribution to the education of future physicians.

Critical Debriefing.—After the open discussion with the patient, the patient leaves the room and the students are debriefed with two attending facilitators. The students identify key issues that the patient illustrates within the four core themes. The debriefing is structured to incorporate principles of adult education which we know enhance effective learning. There is deliberate attention paid to maintaining a safe and supportive learning environment where the students feel comfortable exposing their imperfect skills, personal feelings, biases, and psychological defenses as they grapple with emotions and reactions that inevitably arise during the workshop. The attending facilitators encourage the students to participate in developing learning objectives within the session. Learning is enhanced by a problem-oriented approach where the individual students' past experience and knowledge contribute to the discussions. They are encouraged to reformulate the themes and apply them to other patient encounters. The students get immediate feedback from the facilitators and their peers. The worksheets are collected and both students and patients are asked to evaluate the session and how it affected them.

Results

Evaluations from students have been uniformly excellent, often citing the experience of talking openly with the patient as the most effective aspect of learning. Students' comments indicate new awareness gained in all four thematic areas. They gain insight into the continuum of care that takes place outside of the hospital, and into how satisfying such a physician-patient relationship can be for a primary-care physician.

Even more impressive, however, is the awareness of the importance of communication in learning the patient's story, values, wishes, and fears. In every patient story, students are made acutely aware of the hurtful language used by some physicians. For example, one patient with lymphoma was given his diagnosis by the radiologist who had just read his computed tomographic scan in a crowded emergency room. The patient relates an out-of-body experience of watching the scene take place from up high in a corner of the room. The radiologist said, "You have lymphoma." The patient replied, "Pneumonia?" and the radiologist insisted, "No, lymphoma." Another patient when given the diagnosis of AIDS was told, "You're a plane about to crash, a ship about to sink." These actual examples affect their experience in a more powerful manner than any didactic format.

For the patients, the experience of sharing their stories has been, at times, transforming. Every patient who has participated in the workshops has given strong positive feedback. Issues that have been difficult for them to face before this experience are highlighted and opened for further work. One patient had felt abandoned as a child when her father died, but she was planning on not preparing her children for her death from AIDS. The discussion with the students allowed her to see the parallel needs of herself as a child and her own children. Another patient wrote, "I have come a long way in dealing with my illness, such as when I was asked by one student if I think about death. By trying to answer her honestly and openly, it reminded me of how scared I was when I used to think about death."

Discussion

Recognizing that taking care of dying patients involves the development of cognitive and communication skills and attitudes, the workshop we have developed is only one part of a planned four-year medical school curriculum. The total curriculum will ideally encompass many different aspects of caring for patients with terminal illness. We advocate a developmental approach that builds over the four years to enable students to achieve the ultimate goal of competency in attaining the professional knowledge, skills, and attitudes of caring for the dying patient. Our course is a single component of that effort.

The four-core themes help to create a framework for the students to view caring for the terminally ill patient in the primary-care setting. Since most of their clinical training takes place in the hospital, and the majority of their patients that die do so in the hospital, students are often not aware that imaging studies, transfusions, intravenous medications, chemotherapy, radiation therapy, phlebotomy, oxygen, and pain control may all be arranged as an outpatient. They learn there are many reasons to avoid hospitalization, including patient choice, comfort, cost, avoidance of infection, and privacy. They also learn that there are times when hospitalization becomes necessary, for example, for palliative surgery that cannot be done as an outpatient, treatment of reversible symptoms of disease refractory to outpatient management, like bleeding or febrile neutropenia, or when there are simply no resources available outside the hospital to care for the patient.

In the continuum of care, thinking about a patient's attitudes, beliefs, spiritual needs, and response to illness should start with the very first encounter between physician and patient. With the initial history and physical examination, the physician may uncover risk factors for disease, such as a family history of cancer, that will prompt discussion of a patient's lifestyle or manner of life, motivations, and attitudes about treatment, suffering, and death. The patient's values are explored further in future visits for acute and chronic illness. The continuum of care allows for an opportunity to discuss advanced directives, such as living wills and health-care proxies, in an unthreatening and unhurried time course. Respect for the patient's values guides the physician at all points along the continuum of care and becomes crucial in setting goals when a diagnosis of potential terminal illness is faced. Sometimes a patient's values may differ widely from the physician's and this conflict needs to be identified and addressed. It is important to recognize that a patient's goals may change at any time from aggressive pursuit of cure to aggressive pursuit of comfort only.

It is emphasized to the students that in distinct contrast to this change of goals for the patient, there is absolutely no change in the obligation and role of the physician towards that patient. The same knowledge, skills, and attitudes that characterize a competent primary-care physician, should describe a physician providing comprehensive palliative care. In most training programs there is an emphasis on highly technical treatment, associated with and oriented toward prolonging life. A byproduct of this emphasis has been the learned attitude by students that death, or even a change from cure-oriented goals, represent professional failure. In addition there is a widespread misconception that once the need for curative-oriented technology ends, the remainder of care is unscientific, unchallenging, and hardly an appropriate physician responsibility. This attitude is compounded by the pervasive negative attitude among many residents and attendings who supervise medical students about the professional value of palliative care, an attitude developed in part because of the minimal exposure many of them have had to palliative care teaching.

Within the presentation of the fourth theme, the students are helped to realize that a diagnosis of terminal illness does not necessarily mean certain or imminent death. While there are statistics and experiences with which to counsel the patient and guide the physician, every patient hopes to be the one to beat the odds. Language and timing become important. The physician needs to be honest but not cruel. A certain amount of denial on the part of the patient is protective, but open, honest discussion of death can be liberating. Many writers have addressed the dilemma of whether to disclose a bad prognosis.[11–13] The facilitators emphasize that frank discussion of death, including fear, pain, and readiness, and of the patient's wishes regarding funeral preparation, allows a patient to take control at a time when loss of control seems overwhelming. The physician can and should enlist the help of the patient's loved ones, clergy, and social supports as warranted.

Conclusion

This workshop introduces students in their clinical years to the role of the primary-care physician in the continuum of care that represents the ideal longitudinal physician-patient relationship. The continuum of care includes health maintenance, acute problem oriented visits, chronic disease management, and terminal illness. Patients and families repeatedly express their ultimate fear that once it is clear that their disease cannot be cured, their doctor will lose interest and they will be abandoned. Knowing this, we have an obligation to foster in our students the importance of maintaining the role of primary-care giver during the terminal phase of a patient's illness. Our curriculum is unique in that 1) the emphasis is on the *natural* extension of primary care to *include* the patient's dying; 2) the patient is the *focus*, validating an integral role in decision making; 3) an experiential, learner-centered educational approach is taken where principles of adult learning theory are utilized: a nonthreatening learning environment, active problem solving, and immediate feedback; 4) emphasis is put on communication skills with dying patients, including active listening, appropriate verbal messages, and consistent nonverbal messages; and 5) a democratic leadership style is used in the workshop where the patient, student, and facilitator, each both teach and learn.

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Frequency of Breast Biopsy and Breast Cancer Diagnosis in Central Connecticut—Trends From 1993 to 1997

ANDREW RICCI, JR., M.D. AND THOMAS BANEVER, M.D.

ABSTRACT—The frequency of diagnosed breast cancer at Hartford Hospital has risen 75% from 1993 to 1997 (153 *vs* 87 cases during January-March 1997 as compared to January-March 1993). During the same intervals the frequency of breast biopsies performed also increased 45% (455 *vs* 312 biopsies). The rate of "positive" biopsies has increased slightly (27.9%, 28.3%, 31.5%, 30.7%, and 33.6% for the first three months of each year 1993 to 1997, respectively). When stratified into thirds based on decreasing practice activity of Hartford Hospital surgeons with regard to breast surgery, the "positive" biopsy rates were 28.7%, 31.2%, and 33.0% respectively. Local breast cancer incidence is rising, however surgeons are not "overusing" breast biopsy as compared to recent past practice despite the fact that many more breast biopsies are now being performed.

Introduction

BREAST cancer incidence is rising and it is now estimated that approximately one in eight women will develop breast cancer at some point in their adult lives.[1] Breast biopsy, aimed at investigating a palpable mass or mammographic abnormality, is one the most common surgical procedures performed.[2] To determine whether surgeons were "overusing" this procedure as compared to recent past practice, a study was conducted to address three questions: 1) What is the magnitude of the increased breast cancer incidence for patients diagnosed at Hartford Hospital during the years 1993 to 1997? 2) What was the frequency of breast biopsies performed by Hartford Hospital surgeons during the same period? and; 3) What are the "positive" biopsy rates among surgeons who are most active in breast cancer surgery.

Methods

The Hartford Hospital Department of Pathology's CoPath computer database was searched for all cases with a SNOMED code of T-04 (breast, not otherwise specified) during the interval January-March for each of the years 1993 to 1997. This revealed 3,658 accessions. The nonsurgical cases were sorted out from these raw numbers leaving 2,316 surgical accessions that contained the word "breast" in the diagnosis. The cases were then sorted by the attending physician of record. Three hundred sixty-three further cases were deleted for the following reasons: 1) specimen reflected cosmetic or plastic procedure; 2) specimen was a total mastectomy rather than a biopsy or segmental resection; 3) specimen was not actually a breast biopsy but rather "skin" of breast; 4) specimen consisted of microscopic slides reviewed for a medical or radiation oncologist; 5) specimen consisted of microscopic slides reviewed for a pathologist at another institution requesting consultation; 6) specimen was a stereotactic core biopsy performed by a radiologist; 7) attending physician of record was a nonsurgeon (these were considered "addressograph plate/record keeping errors"). After these deletions a total of 1,953 biopsies remained for the five January-March intervals from 1993 to 1997. These biopsies, sorted by surgeon (coded "A" through "R"), became the case material for the study. Of these, cases that were "positive" ie, diagnosed as breast cancer, were then identified. A "positive" diagnosis included invasive duct carcinoma, invasive lobular carcinoma, ductal carcinoma *in situ,* or lobular carcinoma in situ. Atypical duct and lobular hyperplasia were not included.

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Results

The original 3,658 accessions identified by the SNOMED search consisted of 560, 638, 717, 784, and 959 cases from the first three months of each of the years 1993 to 1997, respectively. After the nonsurgical accessions were deleted this left 350, 412, 470, 453, and 631, cases, and after the other disqualifiers were applied (see Methods) 1,953 cases remained, ie, 312, 321, 397, 384, and 539, respectively. Similarly the number of cancers identified were 87, 88, 125, 118, and 154, respectively. One further correction of these data was made (see below) such that the final revised figures for 1997 were 455 biopsies with 153 carcinomas (Fig. 1). The frequency of diagnosed breast cancer rose 75% from 1993 to 1997, whereas the number of biopsies performed rose 45%.

When the cases were sorted by practice activity of individual surgeons and cumulative "positive" rates were calculated (Figs. 2 and 3) certain information became apparent. Ninety percent of all breast biopsies were performed by one of 18 surgeons ("A" through "R"). The remainder were done by general surgeons (or surgeons in other subspecialties that infrequently performed breast surgery), OB-GYNs, or house staff. The most active tertile (surgeons "A" through "F") performed fully 54% of all the procedures. When the practice of these surgeons were examined on a year by year basis an anomaly was identified with regard to the two most active surgeons (Fig. 2a). Whereas there was a general trend towards greater numbers of biopsies across the board, these two showed a more dramatic increase in biopsy activity in 1997. On closer examination the large increase was due primarily to the performance of office core biopsies. When these were deleted from further consideration (leaving a new total of 1,872 procedures) the number of biopsies performed by surgeons "A" and "B" was more in line with the other surgeons in the most active tertile (Fig. 2b). When considering all biopsies of surgeon "A" (excisional and core) the positive rate was 25.1% whereas when considering only excisional biopsies the positive rate rose to 33.6%. This is consistent with the practice of using core sampling on clinical unsuspicious lesions in an attempt to avert "unnecessary" excisional biopsies.

The trend towards more biopsies over time was not universal. Surgeons "C," "D," and "F" in general performed similar numbers of breast biopsies throughout the period studied. Surgeon "E" has a slightly lower "positive" rate than the other most active surgeons, however, the total number of biopsies was in line with the others in this tertile, so this probably reflects the breast disease in that particular practice rather than an aberrant biopsy practice pattern. Fig. 3 also examines the positive rate across the three tertiles. There appear to be no significant differences. The positive biopsy rate for the remaining specimens performed by physicians and surgeons other than those coded "A" through "R" was 34.3% (68/198). Finally looking at the entire data for all three tertiles over

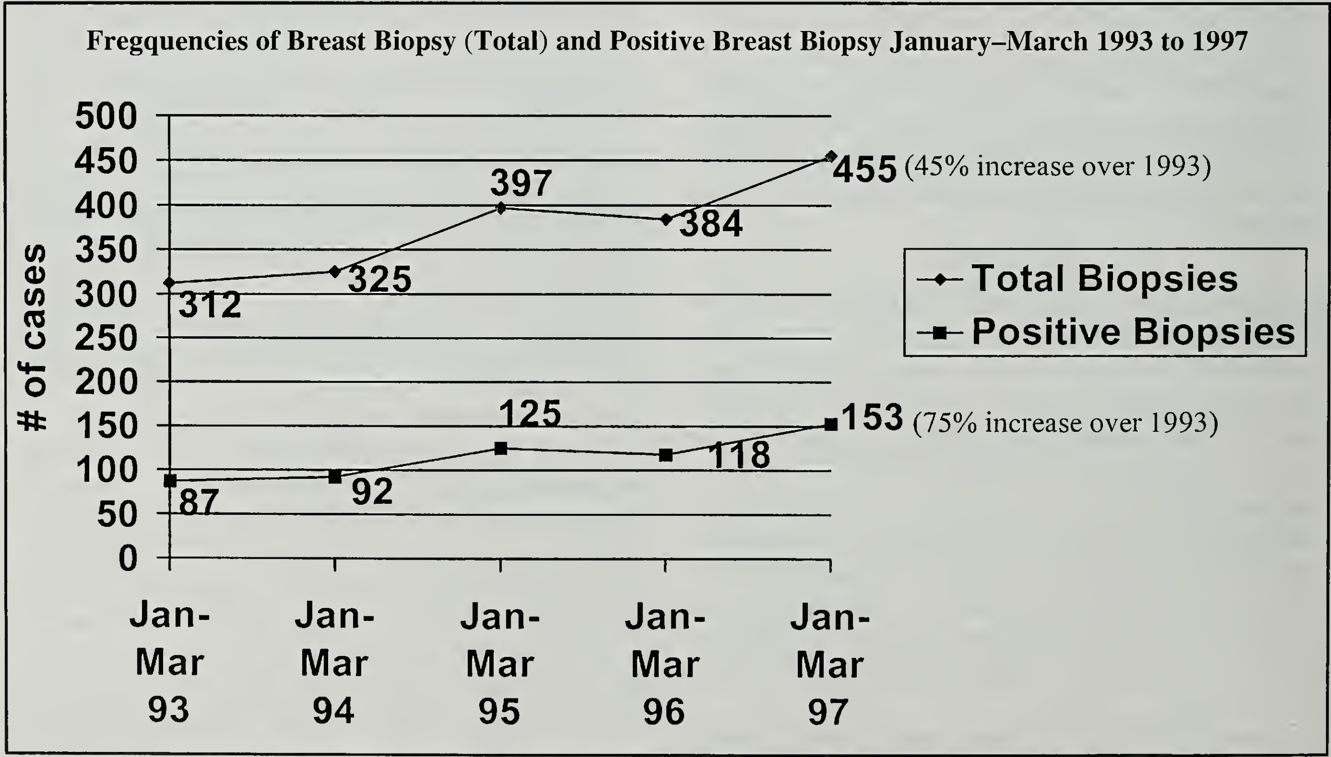


Figure 1.—Frequencies of breast biopsy and positive breast biopsy. Biopsies have increased 45% while positive biopsies have increased 75% from 1993 to 1997.

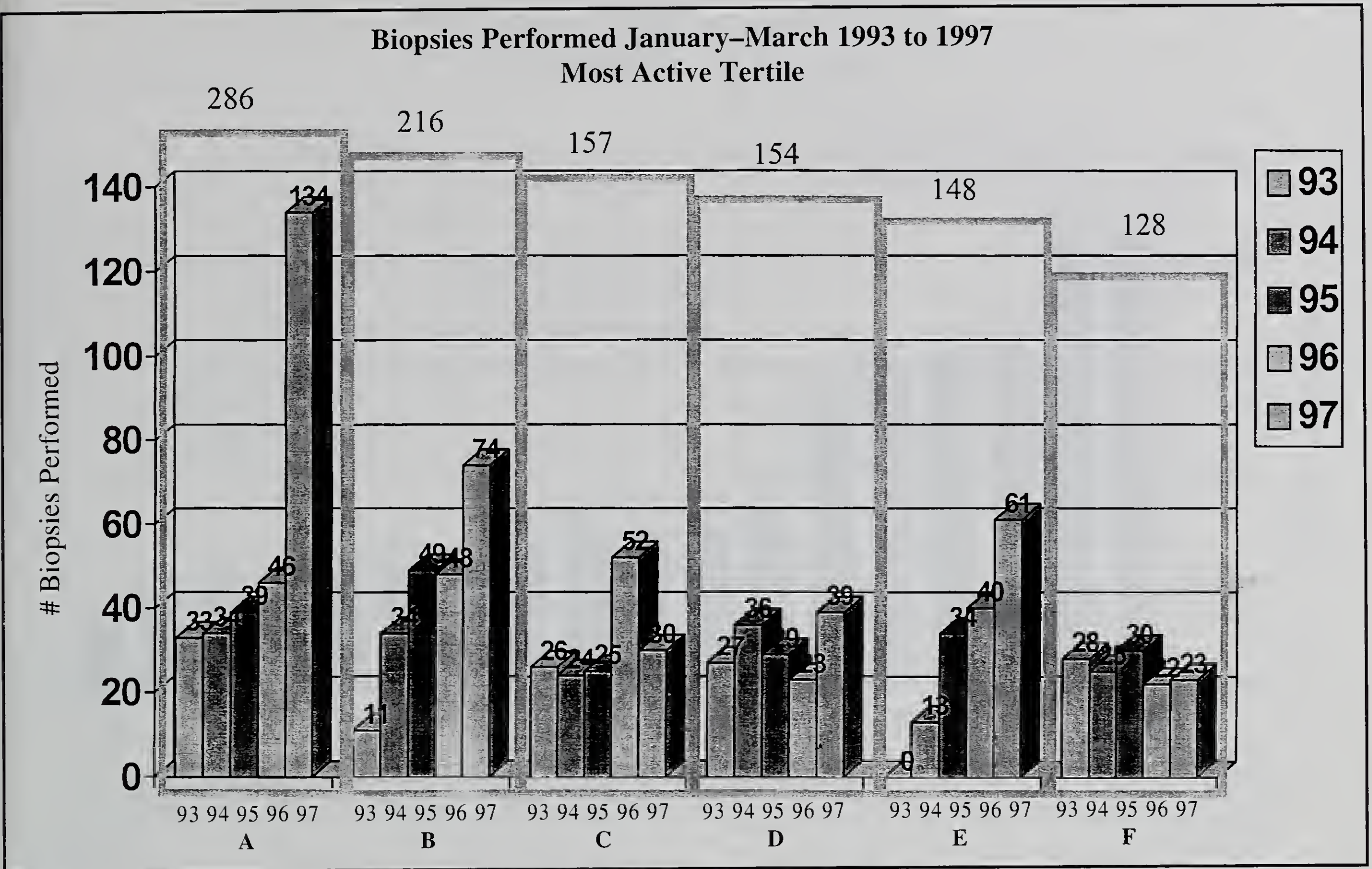


Figure 2a.—Biopsies performed by most active tertile of surgeons. There is a general (but not universal) trend towards more biopsies being performed over time by individual surgeons.

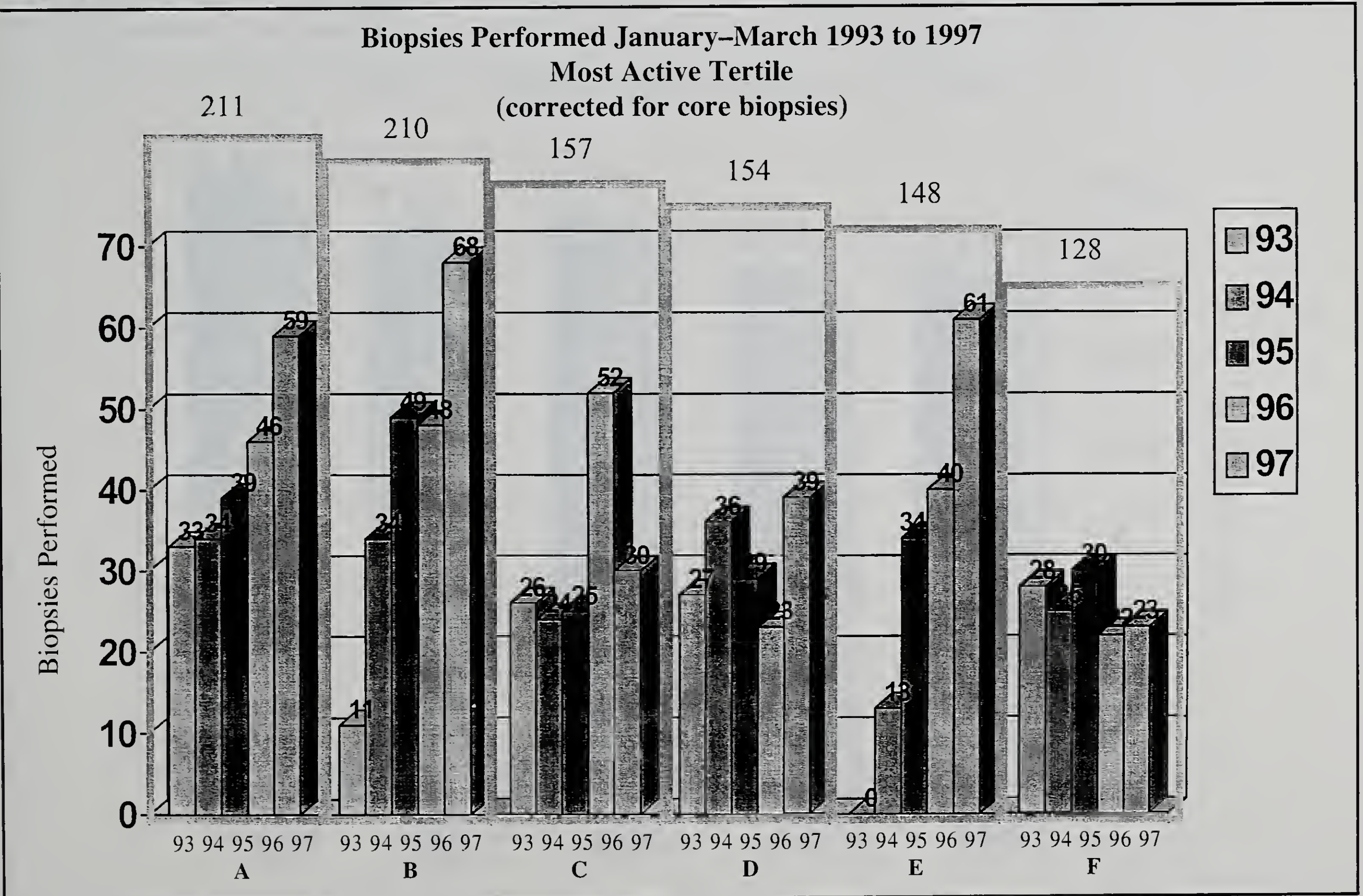
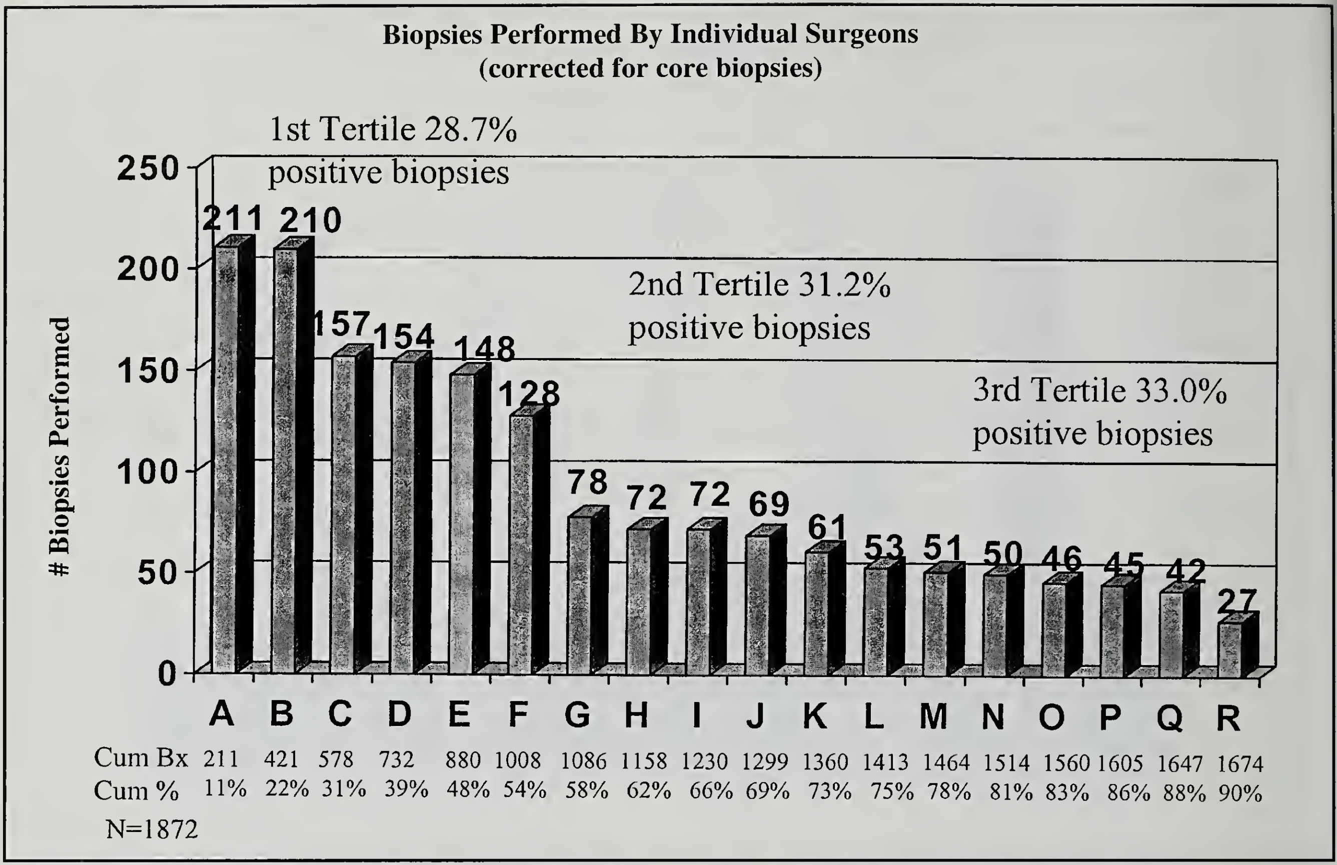


Figure 2b.—Biopsies performed by most active tertile corrected for core biopsies performed in the office.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
Cum Bx	211	421	578	732	880	1008	1086	1158	1230	1299	1360	1413	1464	1514	1560	1605	1647	1674
Cum %	11%	22%	31%	39%	48%	54%	58%	62%	66%	69%	73%	75%	78%	81%	83%	86%	88%	90%

N=1872

Figure 3.—Biopsies performed sorted by individual surgeons and corrected for core biopsies performed in the office. There is no significant difference in positive biopsy rate among the tertiles.

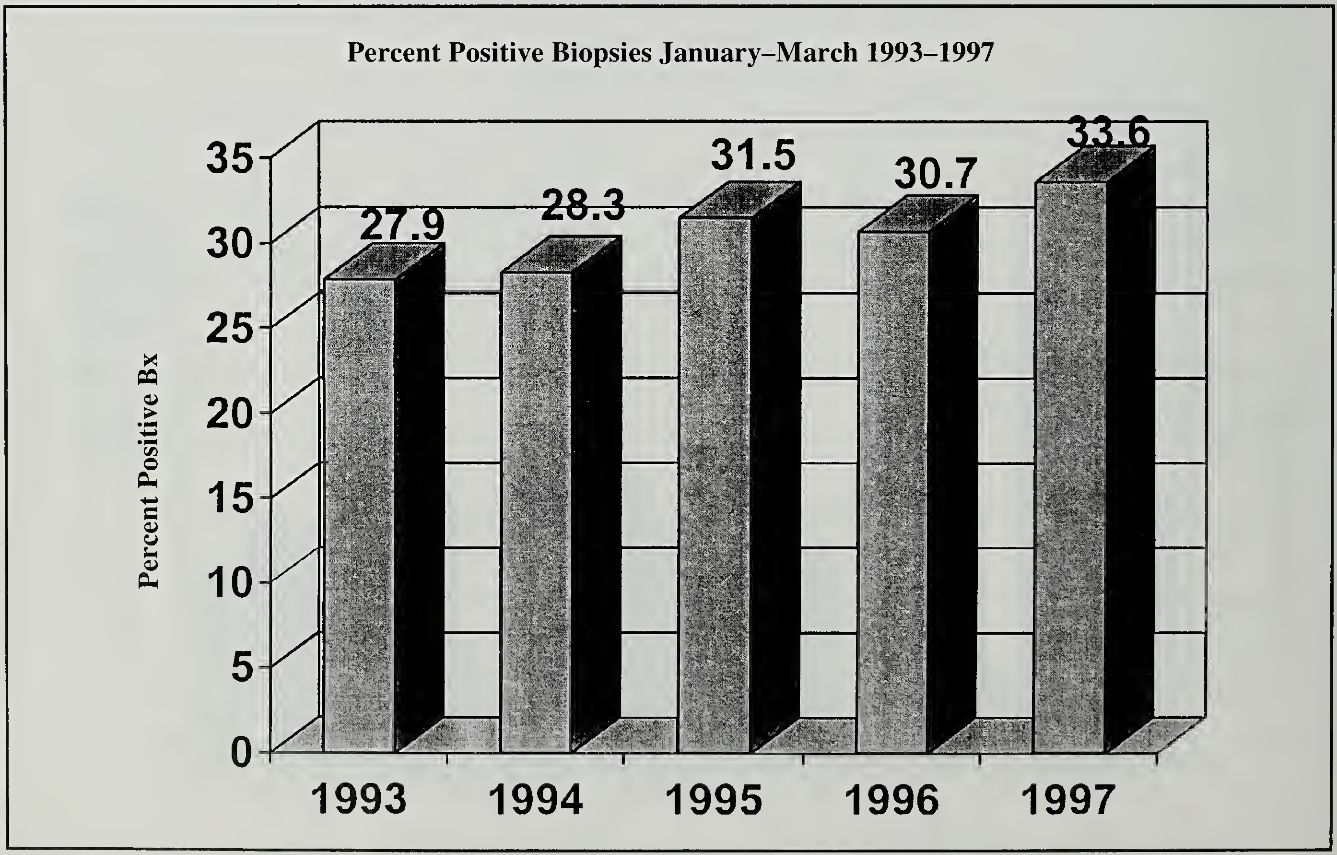


Figure 4.—Percent positive biopsies 1993 to 1997 has remained relatively stable and has even increased modestly (by 20%).

the five-year period studied, the positive biopsy rate was relatively stable although it increased slightly (20%) from 1993 to 1997 (Fig. 4).

Discussion

Given the current emotionally charged environment of a seemingly ever-increasing breast cancer incidence coupled with the large numbers of breast biopsies being performed on a daily basis, it may be appropriate to question, from a tissue review perspective, if surgeons might be "overusing" the breast biopsy procedure. This is a difficult question to tackle. After all what consititutes "appropriate" use of excisional or incisional biopsy in the investigation of a breast lump or mammographic finding? Either of these clinical indicators may be sufficient in themselves to elicit breast biopsy. Still biopsy practice may differ among surgeons of dissimilar backgrounds and levels of expertise. If an increase in biopsy frequency were due only to new surgeons establishing their practices or established surgeons simply performing more biopsies, the number of positive biopsies, as a percentage of the total number of biopsies, would be expected to decrease.

To attempt to address this issue a retrospective study of biopsy practice of the surgeons at Hartford Hospital was performed using the pathology department computer as the database. A sampling of cases for each year 1993 to 1997 were studied. New breast cancer diagnoses for the first three months of the years 1993 and 1997 were 87 and 153, respectively, reflecting a 75% increase. Over the same periods the number of biopsies performed also increased 45% from 312 in 1993 to 455 in 1997. Therefore, during this interval the positive biopsy rate actually rose slightly from 29.7% in 1993 to 33.6% in 1997. Further when surgeons were stratified by tertiles on the basis of practice activity, there were no significant differences in the positive biopsy rate. There is a slight trend towards fewer positive biopsies in the most active tertile, however this was probably due to the breast disease extant in the practices of one or two individuals.

Local breast cancer incidence appears to be rising, consistent with national and statewide trends,[1] however surgeons are not "overusing" breast biopsy as compared to recent past practice despite the fact that many more breast biopsies are being performed. Rather, the increasing frequency of biopsies performed reflects the underlying breast conditions with which patients are now presenting to their surgeons. Although some of the increase in breast cancer frequency in this study might be due to increased referrals from peripheral hospitals, this is not likely to explain the entire increase given the national trends. It is more likely that much of the increased biopsy activity is due to referrals from radiologists for various nonpalpable mammographic abnormalities. This is consistent with the increasing proportion of Tis stage (carcinoma *in situ*) lesions we have seen over the same period.

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Primary Health-care Physicians: Vital Roles in Organ and Tissue Donation

MARGARET B. COOLICAN, R.N. AND MARY A. SWANSON, R.N.

ABSTRACT—The involvement of primary-care physicians is integral to the success of organ and tissue donation and transplantation. Primary-care physicians have a vital role to play in educating patients and encouraging family discussion about organ and tissue donation. A study to determine the practice of Connecticut primary-care physicians relative to providing donation information to patients during routine care was conducted in three phases: 1) validation of current practice of primary-care physicians regarding educating patients about donation, 2) development and distribution of educational materials requested by primary-care physicians, 3) evaluation of primary-care physician practice and educational materials. Most (69% N=310) responding primary-care physicians never discuss organ/tissue donation with patients during routine care and only 5% (N=24) had donation information available. When provided with donation materials, most primary-care physicians left these materials in the waiting room and did not personally discuss donation with the patient. Collaboration between primary-care physicians and organ procurement staff needs to be increased so that primary-care physician's more readily discuss donation with their patients and encourage patients to discuss donation decisions with family members.

Introduction

Dying, death, advanced directives, autopsies, organ and tissue donation … words we would rather not think about for ourselves or our patients. Yet they are a reality and a part of life. Sometimes, no matter how hard we try, patients die. As health-care providers, we have a responsibility to ensure that patients and their families are informed about end-of-life issues. Families need to be provided with the opportunity to have an autopsy performed or to donate organ and/or tissues at the time of death. Providing the opportunity should be no more difficult than telling a patient's family that their mother, husband, or child has died. In fact, physicians who are comfortable talking about donation recognize the value of such discussions since many families view donation as one of the few positive events during a tragic time. After the family acknowledges that death has occurred, participating in a donation discussion may allow the family to focus on something other than the death. It may also help them regain some control often lost in a crisis. Organ and tissue donation may help to bring a family comfort after the death as evidenced by the fact that most donor families would donate again if the opportunity was provided.[1] Although every family has the right to make a decision about organ and tissue donation, many are not offered the opportunity. Some health-care professionals feel that the family is too distressed, in too mucg pain, or would not be interested. When a health-care professional does *not* offer the option of donation to the family, then they have made the donation decision for the family.

The role of the primary health-care physicians (PHCP) can vary in the organ and tissue donation process. A major role may be to provide support during decision making to potential or actual donor families. An understanding and

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active involvement in the donor process may also be important for PHCP support of transplant candidates and/or recipients. In addition, physicians can also have an effect on increasing the number of family discussions about organ and tissue donation prior to a crisis. PHCPs often have a long-term relationship with their patients and can inquire about donation decisions at the time of routine visits. Many patients prefer to receive information from the physicians who provide routine care to them and their family and who will provide this care over a period of many years.[2] Knowing the wishes of a loved one may ease decision making for the family at the time of death. After a death occurs, physicians who continue to care for family members can be helpful in educating the family about grief and supporting them and their donation decision. Research has shown that this information will result in an increase in the number of organs and tissues available for transplantation.[3] Unfortunately, routine discussions about donation are often not as pressing as other health-care issues and many physicians are not well informed about organ and tissue donation and transplantation. Thus a key link to the donation process is broken.

Literature Review

The need.—Each day, more than 50,000 United States residents await life-saving organ transplants, such as hearts, livers, lungs, kidneys, pancreas, and small bowel.

Approximately one third of these patients, or seven to eight each day, will die before an organ becomes available.[4] In addition, thousands of patients wait for tissue transplants. Tissue transplants, while less publicized than organ transplants, provide a proven medical therapy for as many as 450,000 patients each year.[5] Tissues recovered for transplantation include sclera and cornea for sight restoration; skin for burn victims; bone for reconstruction related to trauma, tumors, degenerative diseases, fractures, and dental repair; heart valve replacement; saphenous veins for coronary bypass surgery; and connective tissues, as for Achilles tendon repair.

The success of transplants.—The success of all types of transplantation as a therapeutic modality continues to improve. Current one-year success rates for organ transplants are shown in Table 1 and range from a high of 91% for kidney transplants to 59% for heart/lung transplants.[6] Tissue transplants enjoy the most consistent success because there is little danger of rejection. For instance, over 90% of corneal transplant operations restore the recipient's vision.[7]

Donation and legislation.—The discrepancy between supply and demand for organs and tissues has stimulated considerable legislation. This legislation was developed to ensure a consistent, centralized, and equitable approach to donation and transplantation for both donor families and transplant recipients.

- The Uniform Anatomical Gift Act (UAGA) allows persons to indicate their wishes regarding donation prior to death or allows the next of kin to make an anatomical gift at the time of death. The UAGA also prohibits any physician involved in the procurement process from participating in the declaration of death for the patient.
- The Uniform Determination of Death Act (UDDA) states that an individual who has sustained irreversible cessation of circulatory and respiratory function or all brain function, including the brain stem, is dead.
- The National Organ Transplant Act of 1984 established the Organ Procurement and Transplant Network, a national registry to track and develop statistics on organ donation, transplants, and survival rates. This act also prohibits the buying or selling of human organs and tissues.
- The Omnibus Budget Reconciliation Act of 1986 directs all hospitals which receive Medicaid/Medicare reimbursement to adopt policies of routine referral/required request. Therefore, hospitals must develop policies and procedures to ensure that all potential donors are referred to a procurement agency and all families of medically appropriate patients are offered the option of donation. The Joint Commission on Accreditation of Healthcare Organizations has made this a condition of accreditation.[8]

Potential role conflict.—The importance of physicians, particularly family practitioners and internists, in the organ and tissue donation process has been previously studied.[9] Current practice by primary physicians is to raise the issue of organ donation at the time of death rather than

Table 1.—Organ Transplants Performed and Survival Rates

	1985 No. transplants	**1990 No. transplants**	**1994 No. transplants**	**1 Year Survival 1994**
Heart	719	2,023	2,340	82.4%
Kidney	7,695	9,528	10,622	91.2%
Liver	602	2,570	3,650	68.0%
Pancreas	130	530	102	71.9%
Heart/Lung	30	51	71	59.0%
Lung	20	190	720	68.8%

Table 2.—Survey Results

Surveys returned	12% (n=448)
Of those returning, requested information	43% (n=193)
No written organ and tissue (O&T) information provided to patients during routine care	69% (n=310)
Do not provide information because:	
• No literature available	49% (n=221)
• Patients do not request information	46% (n=208)
• Lack of time	34% (n=152)
• Lack of knowledge about donation	31% (n=139)
• Not their responsibility	7% (n=35)
Lack of adequate information for patients	88% (n=396)
If information available, unsure if adequate	46% (n=210)
Useful for education:	
• Donor card/brochure	84% (n=375)
• Posters	29% (n=129)
• Professional education video	25% (n=110)
• Public Education video	24% (n=107)
• In-service education for staff	24% (n=107)
• In-service education for self	19% (n=84)

during the provision of routine care. Tolle et al indicate that requesting donation at the time of death places the physician in a potential conflict of roles.[9] Conflict for the physician is inherent in the term "requesting donation," which is prevalent in the literature[9,10] and in some legislation (Maine, 1986). Conflict will be perceived when physicians, who are taught to provide care, are asked to request things from their patients or families, particularly when the patient is dying or has died. This conflict, which may lead physicians to avoid the donation process, is based on the premise that the physician is requesting donation for the benefit of another individual, not because it is part of the continuum of care or the right of the patient and family. The *option* of donation is simply that, "an option," and viewing it as such, rather than *requesting* something from the family is key to understanding the success of involvement in the donor process. Therefore, promoting donation as an option and as the responsibility of a physician to his or her patient, rather than as a conflict, may help physicians become more involved with the donation process. One way to emphasize that responsibility, decrease conflict, and counteract the reluctance of physicians to engage in such discussions with patients is to encourage availability of donation materials and the discussion of organ and tissue donation options with patients during routine care. In this way, the patient's wishes can be made known in advance and will serve to lessen the reluctance to discuss donation with the next of kin at the time of death. The physician can then be a better resource to the patient's family when the issue of donation is considered.

Table 3.—Follow-up Survey Results

Surveys returned	28% (n=55)
Remembered the survey	88% (n=44)
Unsure about receiving the survey	5% (n=3)
Did not receive the survey	15% 9n=8)
Of those who received materials:	
• Using materials	68% (n=30)
• Not using materials	25% (n=11)
Reasons: too busy, inertia, no patients, no occasion, no need, too much time and trouble	
• Used if patient interested	2% (n=1)
• No answer	5% (n=2)

Unfortunately, health-care professionals who are not informed or who are uncomfortable with organ donation may also be reluctant to discuss donation with families of potential donors even at the time of death. Thus, surviving relatives are often not offered the opportunity to donate.[11] In a study which assessed the attitudes of primary physician house staff toward organ donation, overall attitudes were positive. However, nearly one-half of the house staff thought they had little knowledge about organ donation or transplantation. Also, few activities focus on educating primary physicians.[9,12] Education of PHCPs is particularly important because research suggests that when unidentified donors were admitted to the services of neurosurgery, neurology, and internal medicine, the percentage of "missed" potential donors was highest among internists.[13] Educational programs can facilitate organ procurement[9,14] and may significantly improve the recovery rate of organs and tissues from cadaver donors.[15] With the implementation of the Patient Self Determination Act of 1991, physicians are now more likely to discuss end-of-life decisions with their patients. These discussions should include the patient's wishes about organ/tissue donation, an important end of-life decision, which is often ignored in these discussions. Also, advanced preparation by the physician will help the family avoid making uninformed decisions at the time of death when they are ill equipped to do so because of their crisis and acute grief reaction.[8] Prior knowledge can also help to lessen the stress that families may feel if the person's donation wishes are not known.[16]

There is little information in the literature which emphasizes the importance and responsibility of the physician to follow a patient's wishes to donate. However, researchers have found that families were more receptive to donation when offered the opportunity to donate by health professionals with whom they had established good rapport.[13] The combined effect of prior knowledge and the rapport that many families have with their physician may be an important factor in increasing the number of actual donors.

Connecticut Physicians: A Study

Methodology.—A recent study by the NorthEast Organ Procurement Organization and Tissue Bank in Hartford, was conducted to further coordination between primary physicians and the public in Connecticut. Primary physicians were encouraged to educate patients about organ and tissue donation during routine care and to encourage patients to discuss personal wishes about donation with their families.

A preliminary survey was developed and pilot tested by two family practice residency programs in Connecticut. After revisions, a cover letter and the survey were sent to 3,654 Connecticut PHCPs. A postcard was included with the survey to enable the physicians to respond anonymously to the survey but to provide their name and address separately if they wished to receive the results of the survey and/or additional information and donation educational materials.

Results .—The results of the survey are shown in Table 2. Educational materials including donor cards and brochures, posters, an informational sheet, *A Guide for Organ /Tissue Donation Discussion,* a patient educational video, and 100 stickers were provided to the 193 PHCPs who requested information. PHCPs were requested to affix a sticker, as documentation on the patient's chart, when a donation discussion occurred. A follow-up survey, utilizing some of the questions in the initial survey was directed to the office manager of the participating 193 physicians five months after the distribution of the educational materials and documentation stickers. The purpose of the second survey was to determine the following:

- use of educational materials
- documentation practices
- change in practice regarding donation discussions
- the perceived effectiveness of the interventions
- need for additional materials

The results of the follow-up survey are shown in Table 3. The donor card/brochure was the material most often offered to patients and found to be most helpful. Only 23% (7) of the respondents who are using the materials discuss donation with their patients, 63% (19) do not discuss donation, and the remainder left the answer blank. Most PHCPs offered donation materials by leaving the donor card/brochure in the examining or waiting rooms. No PHCP is currently using the video. Of those PHCPs who are utilizing donation materials, 27% (8) are documenting their discussions on the patient's chart. When asked if additional materials were needed, 87% (26) said no, while 10% (3) requested donor card/brochure. None of the respondents requested an educational program for their staff.

Discussion

Currently, most PHCPs do not provide written or verbal information about organ and tissue donation for patients, nor do they have it available in their office. In addition, many feel deficient in their knowledge base and lack sufficient time to engage in discussions about donation. If adequately prepared and supplied with appropriate educational materials physicians may be more likely to participate in the donation process and provide information to their patients.

Organ and tissue procurement organizations must consider the importance of collaboration with physicians to educate them and provide donation materials to educate their patients. This collaboration has not been given a high priority in many procurement organizations. Primary physicians are a vital link to encourage patients and families to discuss organ and tissue donation prior to a crisis, and to offer support during the crisis and after the death of a family member. Through collaboration, primary physicians and procurement organizations can positively affect the number of organs and tissues available for donation, decrease the number of patients dying because an organ is not available, ensure the rights of potential donor families to be offered the option of donation, and effectively support the family after the donation.

For more information about organ and tissue donation, please contact the NorthEast Organ Procurement Organization 1-800-874-5215 or the Yale Transplant Center 203-785-4237. All educational materials are available upon request.

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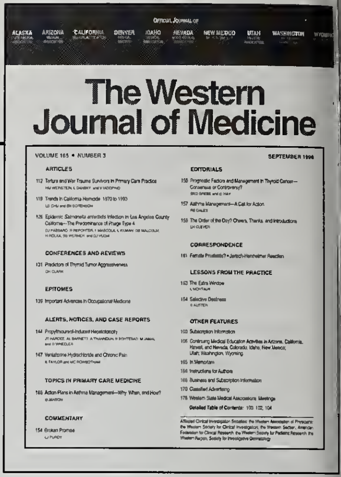
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Important Advances in Clinical Medicine General Surgery

Samuel E. Wilson, M.D., Section Editor

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in general surgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in general surgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on General Surgery of the California Medical Association, and the summaries were prepared under the direction of Dr. Wilson and the Panel.

Percutaneous or Surgical Shunts for Varices Caused by Portal Hypertension

THE clinical introduction of transjugular portosystemic shunt (TIPS) in 1989 led to its widespread use shortly thereafter with claims that it would make the surgical shunt and endoscopic therapy obsolete. Investigations were then undertaken to evaluate its efficacy. Most of the nonrandomized trials addressed stent patency, variceal rebleeding, and encephalopathy; the results showed that shunts established by creation of TIPS are far from permanent, with thrombosis or critical stenosis occurring- in approximately 50% of patients within a year. Continuing shunt surveillance with reinterventions, however, can increase the longevity of the shunt to reduce the risk of variceal rebleeding. The rate of postprocedural encephalopathy is similar to that resulting from total portacaval shunts.

Five prospective, randomized trials comparing TIPS to endoscopic therapy (sclerotherapy or ligation) were recently reviewed. Although methodologic variability limits generalizations, TIPS is apparently more effective than endoscopic therapy in preventing variceal bleeding. This is not surprising, because TIPS corrects the underlying portal hypertension and endoscopic therapy does not. Encephalopathy rates are generally greater after TIPS (approximately 30% to 40%); survival rates are similar. The fifth, and most recently published, randomized trial confirms these findings.

The major limitation of TIPS lies in its potential to generate clotting, a result most likely caused by neointimal hyperplasia. The likelihood for these outcomes may be improved by evolving technological advances; for example, coating stents with material that discourages the development of thrombi.

Surgical shunts have likewise evolved since their introduction in the 1940s; they have proven their effectiveness in permanently preventing variceal hemorrhage. The venerable end-to-side and side-to-side portacaval shunts are examples of total shunts, which divert all portal flow from the liver. Randomized trials of such shunts against medical therapy demonstrated that their positive effect—preventing hemorrhage—was offset by increased incidences of encephalopathy and liver failure.

To circumvent this major disadvantage and to preserve portal flow to the liver, Warren's distal splenorenal shunt was introduced. This is a selective shunt that decreases the incidence of postoperative encephalopathy, especially in nonalcoholic cirrhotic patients.

The most recent advance in surgical shunts is the partial shunt. A small diameter portacaval H-graft is positioned between the portal vein and vena cava and combined with collateral ablation. The fixed resistance of the prosthetic graft provides a constant and safe alternate route for collateral flow. Ideally, portal hemodynamics are minimally altered to attain *collateral substitution.* Prograde portal flow is preserved, the occurrence of encephalopathy is decreased, and variceal hemorrhage is prevented. This operation is suitable for alcoholic cirrhotic patients, because its hemodynamic advantages are maintained over time.

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In many ways, TIPS is closest in concept to the partial portacaval shunt. In each procedure, prosthetic conduits are interposed between the portal and systemic circulations. Both types of shunt permit transvenous catheter access to the portal system for interventional manipulations. TIPS can function as a partial shunt if the conduit's resistance is high enough to maintain portal perfusion of the liver. The advantage of the surgical partial shunt is its provision of long-term relief from variceal hemorrhage without the need for future revision. TIPS has the advantage of making a major intraabdominal operation unnecessary, and in end-stage cirrhosis, TIPS is probably a less intrusive bridge to liver transplantation.

In a randomized comparison of TIPS and the small-diameter portacaval H-graft (partial shunt), TIPS resulted in higher incidences of death, rebleeding, and liver failure.

More randomized trials of TIPS versus surgical shunts clearly are needed. Meanwhile, based on current data, the lengthy track record of surgical shunts, and the existing unrandomized trials of TIPS, it seems reasonable to limit the current use of TIPS to a subset of patients with variceal hemorrhage:

- unacceptable candidates for surgical intervention;
- survivors of failed endoscopic and surgical therapy;
- end-stage cirrhotics awaiting hepatic transplantation;

or

- unstable patients in emergency situations.

Surgical shunts should be used in cirrhotics with good hepatic reserve who have had one episode of bleeding from varices, in whom endoscopic treatment has been deemed unsuitable or has failed. The evidence favors a shunt that preserves portal perfusion of the liver to minimize the chances of encephalopathy and liver dysfunction.

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Endovascular Aneurysm Repair

ABOUT 100,000 abdominal aortic aneurysms and 14,000 descending thoracic aneurysms were diagnosed in the United States in 1984. This number appears to be increasing as the age of our population increases. Aortic aneurysms usually enlarge over time, without accompanying symptoms. If left undetected and untreated, they may rupture, often causing death. Early detection through the screening of high risk patients and elective operative repair of these aneurysms are the keys to the optimal management of this common vascular problem.

Since 1991, the treatment of aortic aneurysms with endovascular stent-graft prostheses has been receiving attention as an alternative to major abdominal surgery. Aneurysm exclusion is performed with a composite stem-graft inserted intraluminally into the aneurysmal aorta from a remote site, usually through the femoral or iliac artery.

Most experience with the use of stem-grafts has been in the treatment of infrarenal abdominal aortic aneurysms. Only about one patient in eight has an abdominal aortic aneurysm configuration with lengths of proximal and distal aortic cuffs able to support a simple tube stem-graft prosthesis. To extend the range of candidates, bifurcated stem-graft prostheses have been developed. Modular stem-graft designs have also been configured to give additional flexibility in transluminal deployment. Transluminally placed endovascular grafts have also been used to treat thoracic aortic aneurysms, aortic dissections, traumatic arterial pseudoaneurysms, traumatic arteriovenous fistulae, and supra- and infrainguinal althero-occlusive disease.

A large number of composite stem-graft devices are in various stages of development; at least eight are in clinical trials. All of these devices share engineering design challenges. The endovascular stent-graft delivery system, either as a simple sheath or a carrying capsule, must be small enough to negotiate the remote artery through which it is inserted. It must also be flexible enough to traverse the often tortuous iliac arteries and lumen of the aneurysm, while avoiding dislodgment and embolization of the laminated thrombus and atheromatous grumous from the aneurysm sac. The graft attachment device must ensure the secure fixation and good apposition to the aortic wall necessary to prevent graft migration, graft detachment, the development of extraluminal channels, and the late development of perianastomotic pseudoaneurysms. This attachment device fixates the graft to the intra-aortic wall with either friction (by pressing against the arterial wall) or some type of hooking mechanism. Ideally, attachment devices should be able to conform to any future potential enlargement of the proximal or distal arteries to which it is juxtaposed. Finally, the graft prosthesis itself must be sufficiently strong to resist dilatation or mechanical breakdown and to allow good tissue incorporation. They have been made mostly from wire forms and Dacron polyester and occasionally from expanded polytetrafluoroethylene (ePIFE) materials, polytetrafluoroethylene (ETFE), or polycarbonate-based polyurethane.

The collaborative efforts of many investigators in this new technology have identified several problems that still must be addressed. Manipulating these devices within the diseased vascular system increases the risk of embolism. The intravascular positioning of these devices may occlude patent lumbar or mesenteric arteries, which may lead to paraplegia and/or visceral ischemia. Or, conversely, these arteries may not occlude, allowing the aneurysm to further enlarge and eventually rupture. Additionally, because most of these grafts are wedged in place, there are risks for perigraft leaking, graft migration, and even delayed aneurysm rupture with insufficient attachment or late dilation of the aorta at the points of fixation. Finally, to fit into these endovascular deployment systems, these graft prostheses must be thin-walled; they may be, however, prone to graft dilatation with loss of integrity over time. When placed intraluminally, the potential for graft dilatation may be limited by the surrounding aortic wall, but its natural history is yet to be defined.

Nevertheless, transluminally placed endovascular grafts present a less invasive approach to treatment of aneurysms and therefore have tremendous intrinsic appeal. There is need for well controlled clinical trials in which the various transluminally placed endovascular graft devices are compared with standard operative treatment methods in groups of patients with aortic aneurysm morphology and similar risk factors. In particular, these studies will need to document the effective long-term treatment of patients with aneurysms having acceptable early and late patency and morbidity and mortality rates. With cautious optimism, it is conceivable that these endovascular devices may replace anywhere between 30% to 70% of current vascular prosthetic grafts, depending on how effective and safe they prove to be.

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Current Risks for Blood Borne Viral Illness in Blood Transfusions

SINCE the discovery of the human immunodeficiency virus (HIV) in 1983, there has been tremendous concern regarding the spread of disease through transfusion of blood and blood products. Blood borne viruses causing specific diseases actually have been well known since the 1950s, when epidemiologists determined that hepatitis B was transmitted through serum. Increasingly sophisticated molecular biology techniques have identified and isolated many more viruses that may be acquired from blood transfusions. The use of these tests to screen blood and eliminate infected units continues to diminish the chances of infecting blood transfusion recipients.

The incidence of transfusion-related HIV infection in the United States has dramatically fallen since testing of all donated blood for HIV-1 and HIV-2 antibodies was initiated in 1985 and 1992, respectively. Of the earliest cases of AIDS (1982 to 1985), 3% were due to contamination of transfused blood products. By 1994, this number had fallen to 1.9%. The decrease is predominately due to testing of donated blood with increasingly more sensitive and more specific assays. It is now estimated that the chances of transfusion-related HIV infection is between one in 225,000 (0.00044%) and one in 60,000 (0.0017%) per transfused unit. Although perhaps due in small part to the imperfection of screening assays, these chances probably represent blood that was donated during the "window period"—an incubation period in which HIV infection has occurred but the body has initiated no measurable antibody response. The risk of transmission due to HIV infection in the window period has been estimated by the American Red Cross to be approximately 2.6 to 6.5 in 1,000,000 (0.00026% to 0.00065%). New technologies such as polymerase chain reaction (PCR) are being studied to determine how to best identify blood infected with HIV in the incubation period, which will decrease to undetectable levels the chances of HIV infection as a result of blood transfusion.

Until recently, the risk of acquiring hepatitis from blood transfusions was between 8% and 12%. Hepatitis C virus (HCV), a lipid enveloped RNA flavivirus (previously known as non-A, non-B hepatitis), was responsible for over 85% of these infections. A 1994 study showed that 4.3% of all HCV infections were transfusion-related. This meant a per unit risk of 0.45% of acquiring HCV infection. With the advent of first-generation tests for screening of HCV, this risk fell to 0.06%; the advent of second-generation tests brought the risk to between 0.02% and 0.05%. Now, with the use of even more sensitive third-generation tests, ongoing prospective studies have yet to show any infection of recipients of recently screened products. These results are only preliminary, but they underscore the increasing safety from HCV of the present blood supply in the United States.

There has also been a tremendous amount of success in preventing infection with hepatitis B virus (HBV) from blood transfusions. Inactivation procedures have resulted in the infection rate plummeting after infusion of labile clotting factors (where HBV infections were nearly invariable because they are pooled from several donors). Despite the fact that, on average, 5.7% (and much higher in some areas) of the population is seropositive for HBV, the American Red Cross annually reports less than 100 cases of transfusion-related HBV infection in the approximately two million patients receiving transfusions. A recent Centers for Disease Control report estimated this risk to be approximately one in 200,000 transfused units (0.0005%), and a recent Canadian study found no serological evidence of transfusion-transmitted HBV infection. With continued donor screening, sample testing, and widespread immunization, these risks should continue to approach 0%.

Another DNA virus that is of special concern is cytomegalovirus (CMV). CMV is extremely prevalent, with seropositivity rates ranging from 20% (in developed but sparsely populated areas) to near 100% (in underdeveloped areas and large, densely populated urban areas). Recent studies in surgical patients have found that transfusion-related CMV infection incidences range from 15% to 30%. When previously CMV negative autologous transplant patients were given blood unfiltered or unscreened for CMV, a 23% seroconversion rate was reported. For patients with previous CMV infection, re-infection with a second strain is associated with increased severity of disease. The vehicle for the virus are the leukocytes, rather than the plasma itself. Fresh-frozen plasma and leukocyte depleted transfusions are successful components in decreasing the incidence of CMV infection, presumably because of the membrane disruption and leukocyte death that results from the freezing process. These findings have been corroborated in recent controlled studies that show no new CMV infections in patients receiving leukocyte-reduced platelets and CMV seronegative blood.

The risk of transfusion-related viral infections has been markedly reduced. Heightened vigilance is necessary to guard against new viruses and known viruses that are mutating to avoid detection. Among the newly discovered viruses are spumaviruses and human foamy viruses (HFV). HFVs, for example, have been implicated in neurological disorders in humans. It is important to remember that any virus not routinely transmitted in the blood, such as hepatitis A or adenovirus, may be infectious if the blood is drawn from the donor during a viremic state. New viral pathogens are sure to arise; therefore we must continue to develop synthetic blood products and molecular technologies that will identify contaminated blood. With continued surveillance and innovation, the blood supply will remain relatively safe and become even more protected from transfusion-related viral illness.

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Sphincter Preservation for Ulcerative Colitis

PROCTOCOLECTOMY with ileostomy was the standard operation for ulcerative colitis (UC) until about 15 years ago. In most patients, restorative proctocolectomy with ileoanal reservoir has replaced the older procedure. Proctocolectomy with ileostomy is still performed in patients who do not qualify for sphincter preservation because of marked obesity, advanced age, inadequate sphincter function, or cancer in the mid- or distal rectum. The goals are eradication of UC, preservation of sphincter function, and construction of a compliant pouch of appropriate size. A number of technical issues remain controversial.

The sphincter preservation technique has evolved. Originally, extensive resection of the mucosa was carried out from the anal and abdominal sides. It became apparent that a lengthy denuded rectal muscle tube was unnecessary and harmful, and a shorter mucosal stripping became the norm. In the last few years, many surgeons have performed no mucosectomy at all as part of sphincter preservation. A double stapling technique is being used that allows placement of the anastomosis within 5 mm of the dentate line in nearly all patients. Some are concerned, however, that diseased rectal or transitional mucosa will be left behind by this method.

The J-shaped pouch is favored by most surgeons today, because it is easy to construct and gives good functional results. A temporary diverting ileostomy remains standard for the majority of surgeons. Other surgeons use an ileostomy; they do so, however, only if there is technical difficulty with the pelvic procedure or if there is a leak when the anastomosis is tested at the end of the procedure.

Postoperative infection, incontinence, and pouchitis are the principal complications of sphincter preservation. There is a spectrum of inflammatory changes in ileal pouches (including Kock pouches), and about 25% of patients have sufficient inflammation at some point postoperatively to qualify for the diagnosis of pouchitis. Its cause is unknown, but multiple factors probably contribute to its development. Pouchitis is almost exclusively limited to patients who had the pouch operation for inflammatory bowel disease, and it is most effectively treated with antibiotics. In 4% to 8% of patients, the procedure ultimately fails because of abscess or fistula, pouchitis, Crohn's disease, incontinence, uncontrolled diarrhea, or other problems, and the pouch is ultimately excised.

Functional results are good but not perfect. The average patient has 4 to 5 stools per 24 hours, and half have at least one nocturnal evacuation. Urgency is experienced in about 50% of patients. Minor incontinence is encountered in 35% of patients, and 20% have more serious leakage episodes. Injury to the sphincters from mucosectomy and/or muscle stretch is one cause of these imperfect results; excision of the rectal wall and the sensors that detect rectal fullness is another. Overall, the quality of life of patients who have undergone this treatment is superior to that of patients who have had proctocolectomy and ileostomy. It is important to note that patients who require colectomy for UC because of refractory disease or the risk of cancer are more willing to accept an ileoanal pouch than a permanent ileostomy. Necessary operations are less likely to be delayed or avoided today than in the past.

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Initial Imaging in the Trauma Patient

RECENT developments with respect to initial imaging in trauma patients have centered on focused abdominal ultrasound (U/S) after blunt trauma, ultrasound/echocardiography for penetrating precordial injury, and computerized tomography and transesophageal echocardiography (TEE) for the diagnosis of torn thoracic aorta.

Focused Abdominal Ultrasound after Blunt Trauma.—Ultrasound of the abdomen after blunt trauma is typically used to simply detect intraperitoneal fluid rather than the presence of specific organ injuries, a study that has been dubbed the FAST (Focused Abdominal Sonography for Trauma) exam. Advantages of this approach relative to diagnostic peritoneal lavage (DPL) are that it is noninvasive, it can be done as fast or faster than DPL, and it can be repeated easily. Compared to CT, FAST exams do not require patient transport, are quicker, and can be done by either surgeons or emergency medicine physicians. Potential disadvantages of the FAST approach are that it requires training to learn how to perform and interpret the exams, and it does not visualize the retroperitoneum well. Even short training courses and a relatively small number of practice examinations, however, are sufficient to adequately train nonradiologists in the technique.

While focused ultrasound after blunt trauma shows promise, some important questions about its use remain. Sensitivity is typically 85% to 95% in recent studies, somewhat lower than the cited 98% sensitivity of DPL. Another concern is that the use of ultrasound in teaching institutions may result in such a decrease in the use of DPL that graduating residents may not be well trained in its use. Instead, these graduates may be trained in using ultrasound, but the FAST approach may not be applicable in small hospitals that care for a limited number of injured patients. It is unclear whether a surgeon or emergency medicine physician can retain adequate skills to perform the technique in a community hospital environment, particularly if the trauma volume is low.

Ultrasound/Echocardiography for Penetrating Precordial Injury.—Stable patients with a penetrating precordial injury pose difficult diagnostic dilemmas. There is always the potential for cardiac injury, and early diagnosis is important. Echocardiography, performed by cardiologists and noncardiologists, is one approach to this dilemma, and it allows rapid detection of fluid in the pericardial space. The FAST approach has not gained widespread acceptance for penetrating abdominal trauma. Early experience with the FAST approach revealed high false negative rates, most likely because penetrating hollow viscus injuries do not result in the rapid accumulation of large amounts of free intraperitoneal fluid. The same ultrasound technology used for FAST exams can be easily and rapidly used to image the pericardial space through a sub-xiphoid view. This approach has excellent sensitivity rates in the few series in which it has been systematically examined. It is rapidly available and can be done reliably by physicians with limited training. Given that formal echocardiography is not rapidly available in most settings after hours, however, use of a simple subxiphoid view by surgeons or emergency medicine physicians makes a great deal of sense.

Computerized Tomography and Transesophageal Echocardiography for the Diagnosis of Torn Thoracic Aorta.—Aortography has traditionally been used to diagnose torn thoracic aortic injuries after blunt trauma. The typical prerequisite for performing aortography has been the presence of a widened superior mediastinum and other suspicious signs on chest radiographs, but this approach has been criticized for a variety of reasons. Suspicious findings on chest radiographs are only about 95% sensitive and, at best, 50% specific. Further, aortography causes delays and is associated with potential complications, such as renal failure. The drawbacks of aortography have led to the search for alternative diagnostic approaches; both chest computerized tomography (CT) and transesophageal echocardiography (TEE) are possibilities.

The use of CT as a definitive diagnostic procedure results in unacceptably high false negative rates. CT can be used, however, for patients with a questionably wide mediastinum on screening chest radiograph. In many of these patients, the widening is related to supine anteroposterior positioning (many multiple trauma patients cannot be positioned upright), to body habitus, or to poor inspiratory effort. In such circumstances, CT is a reasonable approach to detect the presence of a mediastinal hematoma. When no hematoma is found, the likelihood of serious injury to the thoracic aorta is extremely low; thus, further workup is unnecessary. When a mediastinal hematoma is present, the patient will require an aortogram.

TEE has also been suggested for the diagnosis of acute traumatic aortic tears. Several reports cite sensitivities approaching 100%. These encouraging results have not been reported at all centers, however, and some series show disturbingly high false negative rates. Further, a certain percentage of echocardiographic studies either cannot be completed because of technical difficulties or the studies are inconclusive. TEE also poorly visualizes the aortic arch and its major branches. Finally, there is some question as to whether TEE is overly sensitive for small injuries of the aortic intima or media that are of questionable clinical significance. For the above reasons, TEE is not currently a good screening test for torn thoracic aorta. In circumstances in which a patient cannot be moved from the intensive care unit operating room to the angiography suite, however, TEE is useful if there is mediastinal widening on the chest radiograph.

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The Preferred Management of Choledocholithiasis

UP to 10% of patients with cholelithiasis will also suffer from common bile duct (CBD) stones; the optimal management of CBD stones is therefore not a trivial concern. The preferred management of choledocholithiasis has evolved since the early 1990s, when surgeons and patients fully embraced laparoscopy for the treatment of cholelithiasis.

Four primary procedures for the treatment of CBD stones are in use today: open CBD exploration; endoscopic retrograde cholangiopancreatography (ERCP) with sphincterotomy and stone extraction; laparoscopic CBD exploration; and interventional radiology CBD stone extraction. If an experienced surgeon is not available, alternate strategies play a more prominent role; for example, ERCP will likely be utilized more often where there is no surgeon skilled at CBD exploration.

Many presenting signs, symptoms, and laboratory findings suggest CBD stones, but few are particularly accurate in predicting actual pathology. Some 5% to 10% of patients will have unsuspected CBD stones found during routine cholecystectomy although they had no suggestive signs, symptoms, or radiologic evidence. Indeed, the most common reason that patients are referred for treatment of CBD stones is because stones were left behind after cholecystectomy or unsuccessful ERCP.

These CBD stones are rarely visible on diagnostic imaging studies such as abdominal ultrasound or computed tomography (CT) scans. In settings where surgeons with experience are available, laparoscopic cholecystectomy with anticipated CBD exploration is the preferred approach for known CBD stones. Although this procedure is technically challenging, experienced laparoscopic surgeons have a greater than 90% chance of successful CBD clearance with laparoscopic methods. The techniques necessary for using these methods draw largely upon the instrumentation and skills learned by interventional radiologists. Laparoscopic methods often include a series of progressively more complex maneuvers to clear the CBD, concluding with CBD incision, duct exploration, and T-tube insertion—just as in its open operation counterpart.

If a surgeon is not available to perform laparoscopic CBD exploration for known CBD stones, planned preoperative ERCP with stone extraction is the approach that should be used. Endoscopic sphincterotomy or sphincter dilation may be necessary for successful stone extraction. A sensible approach, however, is to do as little as necessary to achieve the desired results; in other words, do not cut or stretch unless required. Fewer than 10% of patients will have unsuccessful ERCP stone extraction. For these patients, subsequent cholecystectomy (laparoscopic or open) must clear the CBD.

When CBD stones are suspected, but not definite, the approach must change. Unfortunately, there are few very good, and many inaccurate, indicators of CBD stones. For example, a total bilirubin level of >20 accurately predicts CBD obstruction. If, in addition, a patient has cholangitis or CBD dilation >10mm, it will be unusual to *not* find CBD stones. Conversely, if there is only one "weak" sign of ductal pathology (such as single liver enzyme elevation), stones will likely be absent from the CBD.

The level of suspicion for CBD stones directs the preferred management of such patients. If clinical suspicion is high, then the management for known stones, as outlined above, applies—with a surgeon's experience playing a major role in the decision of which course to follow. If clinical suspicion of CBD stones is low, one should proceed as outlined for unsuspected, or not definite, stones. If surgeons do not perform routine intraoperative cholangiography during laparoscopic cholecystectomy, they can expect two natural outcomes: few unsuspected CBD stones will be found, and little skill will be gained at laparoscopic intubation and manipulation of the CBD.

The preferred management of stones found unexpectedly at laparoscopic cholecystectomy depends on the surgeon's experience with ductal manipulations. It also depends on the patient's clinical situation. Issues to consider include the number and size of the stones, the size of the CBD, and the amount of surrounding inflammation.

In general, the greater the size or number of the stone(s), the less likely it is that ERCP or transcystic duct laparoscopic extraction techniques will succeed. In these situations, laparoscopic trans-CBD extraction of stones or conversion to open CBD exploration secures the best chance of success, without further interventions and anesthetic. Individual patient circumstances (such as high risk cardiac patients, in whom multiple anesthetics are particularly risky) should weigh heavily in such decision making.

Though controlled data are lacking, it seems easier and safer to open large, dilated ducts than to open and explore small, normal-sized CBDs. For this reason, patients with small stones in small ducts are best managed by either cystic duct extraction during laparoscopic surgery or ERCP extraction following laparoscopic cholecystectomy. ERCP often must follow on the day after laparoscopic cholecystectomy, but it results in greater success and shorter hospital stays than those following open CBD exploration.

When intense inflammation is encountered at cholecystectomy, CBD manipulation is avoided to minimize the risk of CBD injury. Therefore, if CBD stones are found in a patient with intense inflammation involving the hepatoduodenal ligament and its structures, unless stones can be easily flushed through via cystic duct manipulations, it is preferable to provide controlled access to the CBD for later manipulation with either ERCP or transabdominal radiographic techniques. This procedure is accomplished by leaving a small catheter or guidewire through the cystic duct. Moreover, if the surgeon can position the guidewire through the Oddi's sphincter, successful ERCP cannulation and extraction of CBD stones can be performed at a later date. Even if per-oral or percutaneous stone extraction techniques fail, the patient has access and decompression of the CBD while the surrounding inflammation resolves.

Cost and comfort issues have become paramount concerns in today's health-care environment. In this setting, the issues of local clinical expertise and individual patient concerns dominate the management decisions when CBD stones are known, suspected, or encountered unexpectedly. The preferred management of CBD stones continues to evolve as "minimal access techniques" grow in clinical application and acceptance. Intraoperative cholangiography will lead to improved skill with laparoscopic CBD exploration, fewer patients with unsuspected CBD stones after cholecystectomy, and more "one step" methods to manage choledocholithiasis. Conversely, when surgeons do not routinely perform intraoperative cholangiography, they will rely instead on ERCP or radiologic methods of stone extraction. In these cases, multiple procedures will be required, which carry increases in additional costs, risks, and lengths of hospital stays.

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Laparoscopic Cholecystectomy-Associated Bile Duct Injuries

A DECADE after the introduction of laparoscopic cholecystectomy, it is apparent that the most important complication of the operation is injury to the bile duct. This life-threatening problem occurs in about 0.5% of cases; with more than one-half million cholecystectomies performed annually in the United States, over 2,500 biliary injuries are occulting each year. The median age of the patient group is only about 45 years; as such, the consequences of iatrogenic biliary injury in terms of morbidity, mortality, and economic loss are substantial.

Three factors contribute to biliary injury during laparoscopic cholecystectomy: dangerous anatomy, dangerous pathology, and dangerous surgery. While anatomic variants and inflammatory changes are important issues, most intraoperative misadventures are the result of the surgeon's inexperience and poor technique.

A learning curve for laparoscopic cholecystectomy has recently been characterized. Multivariate analyses indicated that the only significant factor associated with an adverse outcome was the surgeon's experience with the procedure. A regression model predicted that a surgeon has a 10-times greater chance of injuring the bile duct during his or her first laparoscopic cholecystectomy than during his or her fiftieth laparoscopic cholecystectomy. The likelihood of iatrogenic injury decreases dramatically during the first 25 procedures and stabilizes at a very low level after 50 procedures.

The majority of serious iatrogenic biliary injuries are due either to misidentification of the common bile duct for the cystic duct or to excessive use of hemostatic metal clips to control periductal bleeding. Conversion to open operation in the face of a difficult dissection and inability to identify anatomy can obviate most biliary injuries during laparoscopic cholecystectomy. Intraoperative cholangiography facilitates accurate delineation of biliary anatomy and immediate recognition of iatrogenic injuries, thus minimizing their severity and allowing their immediate repair.

If not recognized intranperatively, bile duct injuries manifest as internal or external bile leaks, intra-abdominal sepsis, and/or biliary obstruction in the early postoperative period. Slowly progressive jaundice, recurrent cholangitis, and secondary biliary cirrhosis due to ductal stricture are late presentations. Abdominal ultrasonagraphy, computed tomography (CT), and radionuclide biliary scanning are useful initial imaging studies; endoscopic retrograde or percutaneous transhepatic cholangiography, however, are required for precise definition of the lesion. Recently, magnetic resonance cholangiography has been used to delineate and diagnose iatrogenic biliary ductal strictures. The technique is noninvasive and requires no contrast medium injection.

Regardless of the specific type of biliary injury, its management is often difficult and therefore requires a multidisciplinary approach—involving surgeon, gastrointestinal endoscopist, and interventional radiologist. Leakage from the cystic duct stump is the least severe and most easily managed biliary complication of lapiroscopic cholecystectomy. The recognition of leakage usually occurs during the first few postoperative days, and exact anatomic definition of the bile leak requires cholangiography. In this case, endoscopic retrograde cholangiography is preferred, because it is safer and easier than transhepatic cholangiography, and it affords a superior therapeutic opportunity. Treatment consisting of endoscopic placement of a plastic biliary stent across the papilla of Vater for a period of three to four weeks is successful in 85% to 95% of cases. Endoscopic papillotomy is apparently not essential; equilibration of biliary ductal and duodenal pressures is accomplished by the stent alone.

Lateral common bile duct incision injuries, when recognized intraoperatively, can be managed by suture repair using laparoscopic or open techniques. When recognition of the problem is delayed, diagnosis and treatment are similar to that for cystic duct leakage. Late development of a bile duct stricture at the site of injury is an additional concern.

The intraoperative discovery of a bile duct transection or excision should always prompt immediate conversion to an open procedure to repair the injury. In most instances of transection, and in all excisional injuries, a Roux-en-Y hepaticojejunostomy must be used to restore biliaryenteric continuity. If the required surgical expertise is not immediately available, wide external drainage and rapid referral to an appropriate center is the safest course to follow. Patients with major ductal injuries discovered postoperatively by cholangiography should also undergo open surgery for definitive repair. If biliary fistulas, cholangitis, and intra-abdominal sepsis cannot be controlled by means of endoscopic or percutaneous drainage techniques, emergency laparotomy may be required.

The management of bile duct strictures that derive from injuries incurred at laparoscopic cholecystectomy is a complex and challenging problem. Recently endoscopic stenting has been studied as a less invasive alternative to surgical repair. It is crucial to visualize the biliary stricture's exact location, length, patency, and the presence of any associated fistulas or calculi. Both endoscopic retrograde and transhepatic antegrade cholangiography may be required to do so. The approach will depend on the presence or absence of ductal continuity and the location of the stricture. Strictures not amenable to endoscopic dilation and stenting and those failing such therapy should be referred to surgeons with specific expertise in their operative management.

A recent analysis of the mortality financial effect of laparoscopic cholecystectomy-related bile duct injuries has identified a mean cost of over $51,000 for care to repair the injuries. Approximately one-half of the total charges are for diagnostic and interventional radiology services. The mean cost for immediately recognized and repaired injuries was less than $23,000, while that for reoperation after failed earlier repair was more than $130,000. The overall 4% short-term mortality rate for iatrogenic bile duct injury was typical for this morbid and costly complication.

Although laparoscopic cholecystectomy has established its place as the treatment of choice for the majority of patients with symptomatic gallbladder disease, the complications of bile duct injury continue to claim young and productive lives and cost millions of dollars each year. Proper training and experience, routine use of intraoperative cholangiography, and a low threshold for conversion to open operation are the best preventions currently available. Immediate recognition and initial repair by an expert biliary surgeon offers the patient the best chance for an optimal recovery.

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Laparoscopic Colon Surgery

IN the early 1990s laparoscopic colon surgery was shown to be technically feasible, and it has been applied to the management of malignant conditions and benign diseases of the colon. Because it involves both resection of part or all of the organ and restoration of gastrointestinal continuity, laparoscopic colectomy is a technically difficult operation. It requires a skilled and interested surgical team for its successful completion. The variability of the intra-abdominal location, the need to reposition instruments and ports, the sometimes unanticipated location of the pathology, the required control of vascular structures, the size of the specimen, and the extent of resection of colorectal cancer further contribute to the complexity of these techniques. In addition, the number of colorectal operations performed by many surgeons is inadequate to allow a safe "ascent" of this well recognized learning curve. These difficulties have slowed the widespread use of laparoscopic colon surgery.

The benefits of a laparoscopic approach have not been unequivocally demonstrated. Numerous single institution studies have shown a reduction in the rate of postoperative wound complications, shorter hospitalization, less blood loss, and quicker return of bowel function. However, even in centers with experienced surgeons, operating times are longer and operating room costs are higher than for comparable open operations. Shorter hospitalization may offset these differences, although cases requiring conversion to open procedures escalate total cost by 20% to 25%. With most series reporting a conversion rate of 15% to 25%, overall cost savings have not been realized.

Sigmoid resection for diverticulitis is the most common colon operation performed for benign disease in the United States. Because the disease process can be associated with inflammatory changes and adhesions, the laparoscopic approach is not suited for relatively inexperienced surgeons. Laparoscopic colorectal surgery for other benign diseases (diverticular disease, benign tumor, reversal of Hartmann's procedure, sigmoid volvulus, rectal prolapse) has gained widespread use in a few specialized centers.

In 1997, there were 131,000 new cases of colorectal cancer, making it the most frequent indication for large bowel surgery in the United States. There are three potential applications of laparoscopic surgery in colorectal carcinoma: diagnostic and staging purposes, palliative therapy, and curative resection.

Prospectively accrued data indicate that colonic resection for cancer can be adequately performed by laparoscopy. Similar length of bowel resection, comparable lymph node resection, and negative margins are obtained with laparoscopic or open colectomy. However, a disturbing number of port site tumor recurrences has led to questioning of the appropriateness of performing laparoscopic colon resection with intent to cure for colon cancer. It is unclear if these laparoscopic wound site recurrences represent an increase over wound recurrences seen following conventional open surgery. Long term follow-up in patients with colon cancer treated by laparoscopic colectomy is not available. Early outcome data from a multi-institution retrospective study with three year follow-up indicates cancer-related death rates of 4% for Stage I, 17% for Stage II, 31% for Stage III, and 70% for Stage IV. This early outcome is comparable with conventional surgery for colorectal cancer. Currently, an appropriate approach is to perform laparoscopic colectomy only as part of a prospective investigational protocol for the treatment of curable colorectal carcinoma. Several large multi-institutional prospective randomized studies are currently underway, but are still in the patient accrual phase.

It is likely that the answer to these and other issues will be forthcoming in the next decade. Currently, laparoscopic surgery for colorectal disease should be conducted by experienced surgeons for benign disease or palliation of malignant disease, and should be further scientifically studied for potentially curative malignant disease.

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DRUG INFORMATION UPDATE: HARTFORD HOSPITAL

Formulary Review of the Carbapenems: Comparison of Imipenem/Cilastatin and Meropenem

MARK A. RICHERSON, PHARM.D., PAUL G. AMBROSE, PHARM.D., RICHARD QUINTILIANI, M.D., AND CHARLES H. NIGHTINGALE, PH.D.

Introduction

THE carbapenems, which belong to the beta-lactam class of antibiotics, exhibit a broad-spectrum of antibacterial activity, including aerobic gram-positive, gram-negative, and anaerobic organisms. Because of their extended spectrum of microbiological activity, they have become an alternative to combination antimicrobial therapy for a number of serious infections.

Imipenem/cilastatin (Primaxin®, Merck Pharmaceuticals), introduced in 1986, was the first carbapenem available for clinical use. Imipenem is combined with cilastatin to inhibit drug inactivation by hydrolysis in the brush border of the proximal renal tubule and to protect the kidney from the toxic effects of imipenem.[1,2] While a relatively safe agent to use, imipenem use has been associated with central nervous system stimulation. Seizures have been reported in patients who receive this agent at too high or frequent dosage, especially those with renal impairment.[3] For these reasons, researchers have sought new carbapenem moieties that eliminate or, at least, reduce these problems, but yet maintain the drug's intense and broad microbiological activity.

Meropenem (Merrem®, Zeneca Pharmaceuticals), introduced in 1996, is the second carbapenem antibiotic available in the U.S. In this communication, we compare meropenem and imipenem with particular attention to toxicity, microbiological activity, pharmacokinetics, clinical usage, and pharmacoeconomics.

Microbiology

Two generalizations can be made about these carbapenems: first, imipenem has slightly lower minimum inhibitory concentrations (MICs) against gram-positive aerobes and second; meropenem exhibits somewhat lower MICs against gram-negative aerobes. The clinical relevance of these microbiological differences, as will be discussed later in this review, is negligible considering the pharmacodynamic properties of this class of antibiotic. Although the National Committee of Clinical Laboratory Standards (NCCLS) has not yet formally established sensitivity breakpoints for meropenem. The Food and Drug Administration (FDA) has recommended breakpoints identical to those for imipenem, (eg, ≤4 mg/L sensitive, 8 mg/L intermediate, and ≥16 mg/L resistant). Both agents are active against most anaerobic and aerobic bacteria of clinical significance. Meropenem's modest increase in antipseudomonal activity compared with imipenem may be due to its high affinity for two penicillin binding proteins ([PBPs] PBP2 and PBP3), while imipenem primarily shows high affinity only for one (PBP2). Typically, against *Pseudomonas aeruginosa* the MIC50's of meropenem are 0.5-1 mg/L while those for imipenem are typically one to two tube dilutions higher.[4,5] Neither agent shows significant activity against methacillin-resistant *Staphylococcus aureus* (MRSA), *Enterococcus faecium*, and *Stenotrophomonas maltophilia.*

Although it is tempting to conclude from *in vitro* microbiological observations that meropenem is a preferential choice over imipenem, in the treatment of *P. aeruginosa* infections, most infectious disease clinicians prefer combination therapy of an aminoglycoside (eg, gentamicin, tobramycin, amikacin) with either an antipseudomonal penicillin (eg, piperacillin, piperacillin/tazobactam, ticarcillin, ticarcillin/clavulanate) or an antipseudomonal cephalosporin (eg, ceftazidime, cefepime). Additionally,

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Table 1.—Pharmacokinetic Parameters of Imipenem and Meropenem in Adults

	Meropenem		Imipenem	
	500 mg	**1000 mg**	**500 mg**	**1000 mg**
Half-life (hrs)	0.88	0.98	0.90	1.11
Vss (L)	19.2	12.5	15.9	14.4
AUC† (Mg/L/Hr)	33.6	90.8	41.7	92.5
Cl (mL/min)	252	188	203	183
Urine recovery (%)	64.5	75	64.8	74

in serious pseudomonal infections, where maximal microbiological activity is necessary, combination therapy with an aminoglycoside can also be used with carbapenems. Consequently, once an aminoglycoside is given with either meropenem or imipenem, it is unlikely that there will be any difference in microbiological activity against *P. aeruginosa,* emergence of resistant strains, or differences in clinical outcomes.

Imipenem is significantly more active against *Enterococcus faecalis* compared with meropenem. The MIC50's typically are 4 and 0.5-2 mg/L for meropenem and imipenem, respectively.[4,5] The relevance of this difference also has to be questioned for the same reasons we doubt the importance of meropenem's slightly greater activity against *P. aeruginosa.* Since both imipenem and meropenem exhibit only bacteriostatic activity against this organism, neither agent should be given alone in the treatment of serious systemic enterococcal infections. To achieve bactericidal activity, an aminoglycoside must be co-administered with the carbapenem, and then it is likely that any difference in activity against *E. faecalis* is negated. It should also be stressed that synergy against enterococci is observed when an aminoglycoside is combined with a penicillin, such as ampicillin or piperacillin, rather than with a carbapenem.

Table 2.—Pharmacokinetic Parameters of Meropenem in Full-term Neonates and Children

	Neonate	Children
Half-life (hrs)	2.04	0.96
Vss (L)	0.48	0.24
Cl (mL/min/kg)	3.15	3.66
AUC† (mg/hr/L)	134/199*	72/133*
Cmax§ (mcg/mL)	40/79*	56/92*

*20mg per kg/40 mg per kg
†area under the concentration time curve
§maximum serum concentration

Burkholderia cepacia, a metallo-beta-lactamase producer,[6] is often highly and multidrug resistant when isolated from bronchopulmonary secretions of patients with advanced chronic lung disease. Colonization with multidrug-resistant phenotypes has reached epidemic proportions in cystic fibrosis patients, often resulting in infection and significant mortality in this population. Meropenem's MIC50 for this organism is 2 mg/L as compared with 8 mg/L for imipenem.[5] Using an agar dilution technique and FDA sensitivity breakpoints, Bauerfield reported 95% of 38 isolates of *Burkholderia cepacia* grown from the sputa of cystic fibrosis patients were sensitive to meropenem.[7] Perhaps of clinical significance is the observation that a metallo-beta-lactamase, isolated from *Burkholderia cepacia* was >90% inhibited by 0.1mM of tazobactam and clavulanic acid.[6] Thus, one of these beta-lactamase inhibitors or products containing them (eg, ticarcillin/clavulanate [Timentin®], amoxicillin/clavulate [Augmentin®] and piperacillin/tazobactam [Zosyn®]), in combination with meropenem may be useful in the treatment of this increasingly difficult pathogen. At the moment, there are no clinical data to support this approach.

Pharmacokinetics

The pharmacokinetic parameters of imipenem in adults and meropenem in adults, children and neonates are presented in Tables 1 and 2.[8,9] Imipenem pharmacokinetics vary with degree of renal function. Following a 500 mg dose in patients with glomerular filtration rates (GFR) between 30 and 80 mL/min, serum half-life and area under the concentration time curve (AUC) increase from 0.9 to 1.6 hours and from 41.7 to 55.33 mg/L/hr, respectively.[9,10] In patients with severe renal failure, (GFR $\leq$ 20 mL/min), serum half-life increases to 2.49 hours, as does AUC, to 158 mg/L/hr. Plasma clearance and urinary excretion decrease to 59 mL/min and 7.1%, respectively.[11]

Like imipenem, meropenem's pharmacokinetics vary with degree of renal function. Nearly two-thirds of a dose of meropenem is excreted in the urine, primarily via glomerular filtration (65%), and approximately 35% via

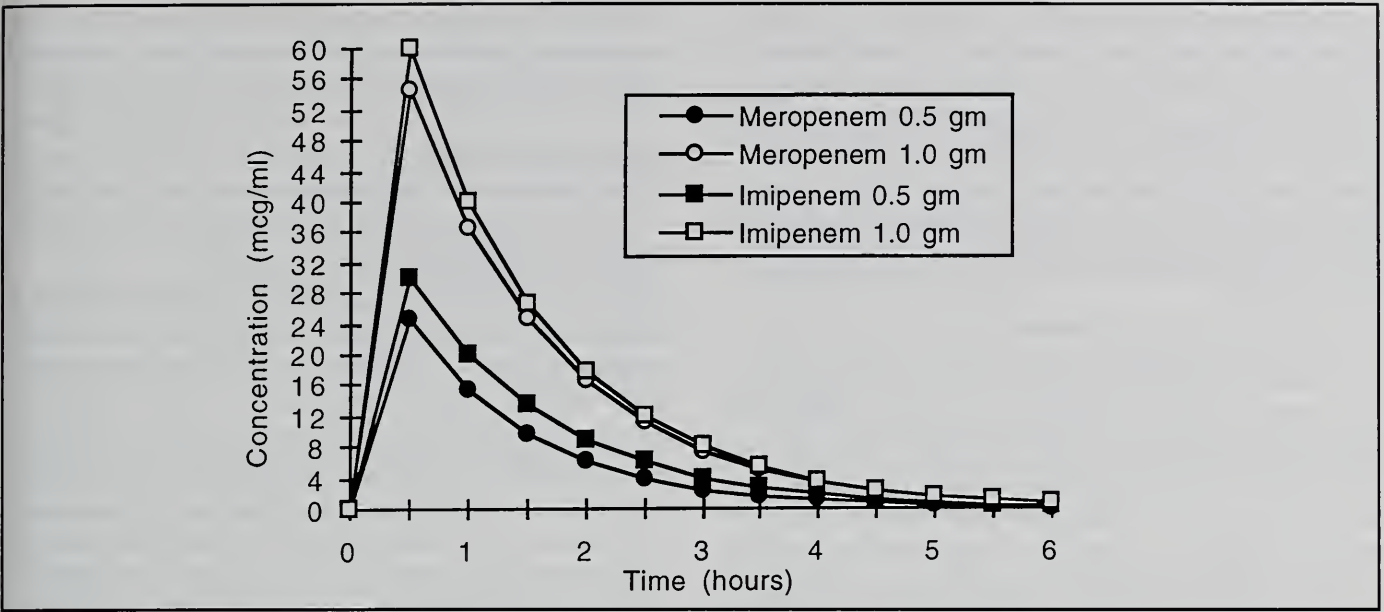

Figure 1.—Simulated serum concentration vs time profile of Meropenem and Imipenem following a 30-munute intravenous infustion.

tubular secretion.[12] In patients with creatinine clearance of 30 to 50 mL/min, serum half-life and AUC increased significantly, from 0.88 to 3.36 hours and from 33.6 to 74.6 mg/L/hr, respectively. Plasma clearance decreased markedly from 252 to 78.2 mL/min, as did the recovery rate from urine (33.2%). In patients with more severe renal dysfunction, creatinine clearance $\leq$ 30 mL/min, serum half-life and AUC increased further, to five hours and 186.8 mg/L/hr, respectively. Plasma clearance and the recovery rate of meropenem from the urine decreased to 49.8 mL/min and 28.0%, respectively, after a 500 mg dose.[9,13]

Pharmacodynamics

An accurate prediction of clinical outcome requires the use of pharmacodynamic concepts that integrate microbiology, pharmacokinetics and the mechanism of bacterial killing. Pharmacodynamic studies have conclusively demonstrated that beta-lactam antibiotics exhibit concentration-independent or time-dependent killing. Once the concentration exceeds the MIC of the pathogen, killing occurs at a zero order rate, and increasing drug concentration does not result in a proportional increased rate of kill.[14] Thus, the goal with beta-lactam agents is to keep their time or duration above their MIC for pathogens for as long as possible in any one dosing interval. How long the levels should remain above MICs during any one dosing interval remains controversial. Animal models of infection indicate that carbapenems should remain above the MIC for approximately 35% to 40% of the dosing interval to achieve clinical success.

Time *vs* plasma concentration data of imipenem and meropenem are presented in Fig. 1. Following a 500 mg intravenous dose of imipenem every six hours, serum levels remain above the MIC90 of most organisms over the entire dosing interval. Against *Pseudomonas aeruginosa*, however, imipenem serum concentration's time above the MIC is less than 100% but greater than 40% of the dosing interval.

Following a one gram dose of meropenem every eight hours, serum levels remain above the MIC90 of most organisms over the entire dosing interval. Again, as with imipenem, serum concentration time above the MIC is less than 100% but approximately 40% for *Pseudomonas aeruginosa.* Unlike imipenem, however, meropenem has been promoted as a drug which can be safely given at a one gram dose in patients with normal renal function. Like imipenem, to avoid the likelihood of CNS toxicity, dosage adjustment is required in patients with abnormal renal function.

Dosage and Administration

The total daily dose, as recommended by the manufacturer, of imipenem /cilastatin is based upon type, severity of infection, and susceptibility of the organism(s) involved and is adjusted based upon renal function. This requires the clinician to utilize cumbersome dosing tables as provided in the manufacturer package insert. The concept of basing dose upon severity of infection makes little sense from a pharmacodynamic perspective as discussed above, since, like all beta-lactams, carbapenems, exhibit concentration-independent killing.[9] Further, the somewhat arbitrary classification of severity of infection is not related to the sensitivity of the bacteria to the antibiotic.

In adult patients, meropenem is dosed one gram every eight hours and also requires adjustment in patients with renal insufficiency. For pediatric patients from three months of age and older, the recommended dose is 20 or 40 mg/kg every eight hours (maximal dose is 2 g every eight hours), depending on the type of infection (intra-abdominal or meningitis). Additionally, in a study in which 165 patients received meropenem by bolus injection, the investigators noted no significant adverse infusion related events.[15] Therefore, unlike imipenem/cilastatin, which is associated with nausea and vomiting upon rapid administration,[15] meropenem may by administered via bolus intravenous injection.

Toxicity

Seizures due to imipenem are dose-dependent and have been noted mainly in patients with renal insufficiency, pseudomonal infection, underlying seizure disorder, and overdosage. The manufacturers report the overall incidence of seizures for imipenem and meropenem to be closely similar, 0.4% and 0.5%, respectively. The incidence of imipenem induced seizures reported in the literature has been significantly higher. In a study of over 3,000 patients, Calandra et al found that 1.8% of patients receiving imipenem experienced a seizure.[3] Overdosage secondary to failure to adjust for decreased renal function, use in elderly patients with CNS infection, neoplasm, and history of seizure disorder correlated with the occurrence of seizure. It must be stressed that the lower propensity for meropenem to produce seizures has been shown only in animal studies. Whether the incidence of seizures in clinical practice with this agent will be less than that of imipenem remains to be determined.

Clinical Use

As compared with meropenem, imipenem/cilastatin has a broader range of currently approved indications, including; lower respiratory tract infections, urinary tract infections, gynecological infections, bacterial septicemia, bone and joint infections, skin and skin structure infections, and endocarditis in adult patients. It is predicted that, in time, meropenem will have similar indications. In addition to having FDA approval for the treatment of intra-abdominal infection, meropenem is also approved for use in pediatrics and in meningitis. Although meropenem has an indication to treat meningitis caused by *Streptococcus pneumonia, Haemophilus influenzae* (beta-lactamase and non-beta-lactamase producing strains), and *Neisseria meningitidis*, less expensive and equally efficacious alternatives exist, eg, third-generation cephalosporins. Generally, carbapenems have no role in community-acquired infections due to the rarity of pseudomonal or enterococcal involvement.

Pharmacoeconomic Considerations

From an institutional or hospital perspective, the relevant direct medical costs that should be considered in choosing one of these agents for formulary consideration include the costs of drug acquisition, preparation and administration, treatment failure, and adverse drug events. As treatment failures and adverse event are considered equal between imipenem/cilastatin and meropenem, these costs can be omitted from the analysis. Meropenem and imipenem/cilastatin are priced such that daily drug cost, in patients with normal renal function, are equal. As a result, the costs of preparation and administration are the determinants of pharmacoeconomic benefit.

Data derived from a time-motion study performed at Hartford Hospital found that the total cost of a single intermittent dose of antibiotic is $3.37, excluding drug cost.[16] Thrice daily *vs* four times daily dosing for meropenem and imipenem/cilastatin, respectively, results in a 25% reduction in cost of drug therapy if meropenem is the preferred agent. Based upon intermittent infusion of meroponem, a cost avoidance of $1,469 may be achieved in our hospital. If all doses of meropenem were administered via direct intravenous injection, additional savings up to $4,214 would be possible.

Summary

In comparison with imipenem, meropenem exhibits closely similar microbiological activity. Although meropenem has slightly greater gram-negative activity against organisms, like *Pseudomonas aeruginosa and Burkholderia cepacia*, imipenem demonstrates more intense gram-positive activity, particularly towards *Enterococcus faecalis* which may reduce or even cancel out, the clinical relevance of these microbiological differences. However, an aminoglycoside is usually added in the treatment of serious infections from these bacteria.

The pharmacokinetics of these two agents are also closely similar both in normal healthy volunteers and in patients with normal or impaired renal function. Moreover, there is little, if any, difference in the acquisition costs for meropenem and imipenem in most hospitals.

Cost-avoidance with meropenem is, therefore, mainly the result of less frequent dosing and the ability to administer meropenem by rapid intravenous injection. Additionally, meropenem's FDA approved indication for central nervous system infection offers an additional advantage when compared to imipenem/cilastatin. It was for these reasons that our hospital's Pharmacy and Therapeutics Committee replaced imipenem/cilastatin with meropenem.

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CORRECTIONS

In the January issue of *Connecticut Medicine* (*Conn Med* 1998; 62:25-8) under **Drug Information Update: Hartford Hosptial,** the manuscript "Antiretroviral Therapy: An Update" had the following errors:

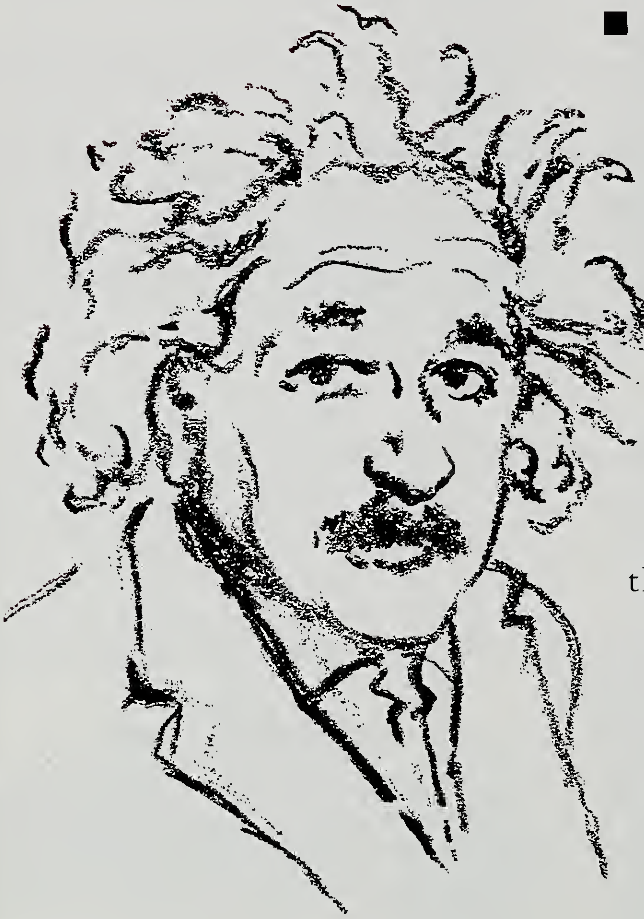
On page 25; paragraph one, line four, the word Institutes should have read Institute; the last line of authors information, G.Gougse should have read G. Gousse; paragraph two, line four, the word then was removed; in the paragraph under the heading **Drug Therapy**, line four and five, the phrase (see below) was omitted.

On page 26; paragraph two, line six, p4S0 should have read p450.

On page 27; in the boxed information, column two, line five read nevi rapirapine instead of nevirapine, in Table 2, column two, under Dose, Indinavir, read 88mg q8h instead of 800mg q8h; column 5, Bioavailability, Saquinavir read four instead of 4.

On page 28; the table should have been labelled Table 3.

Intelligence



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Address for White Coat Ceremony: New York Medical College Convocation

NOEL I. ROBIN, M.D.

I WANT to tell you what an honor it is to be here today and to thank you for the privilege of addressing you on this very special day. As fulfilling as it may be to look back on one's own life and feel that one has achieved his or her idealized goals, unless those accomplishments are passed from one generation to the next, unless the fruits of one's labor and the learning extracted from those fruits are passed to future generations of physicians, then those accomplishments remain within the confines of one's own lifetime. Indeed, the greatness of our profession lies in its commitment to this seamless but inexorable process, and it is the inherent responsibility of those within the profession to foster this tradition in perpetuity. This process can be apparent as in that special moment when the surgeon's scalpel is confidently passed to a resident in training or when critical judgments must be made by young physicians who but a brief moment ago were compiling lecture notes in a didactic biochemistry class. It can be symbolic as in this ceremony today when we bestow upon you the garment that is so meaningful to the profession of medicine. We thus do what generations of other physicians have done in the past and will continue to do in the future. Physicians, who in fulfilling their own destinies, achieve the ultimate fulfillment in bequeathing the essence of their professional lives and teachings upon those who will ultimately carry on.

I must share with you a poem I first learned in the sixth grade at P.S. 191 in Brooklyn (and I must give due recognition to a very special teacher, Mr. Harold Martin, for instilling a love of literature in his students). It is called "My Heart Leaps Up" and was written by William Wordsworth, and it is a poem that ever so often has held a special personal fascination for me. It goes as follows:

> My heart leaps up when I behold
> A rainbow in the sky:
> So was it when my life began;
> So is it now I am a man:
> So be it when I shall grow old,
>   Or let me die!
> The Child is father of the Man:
> And I could wish my days to be
> Bound each to each by natural piety.

It is the line, "The child is father of the man" that has had this special fascination. Surely one interpretation is that as a child, you will ultimately give rise to the person who will be you as a youth. That youth will then give rise to the young adult, and thus in an orderly and sequential manner will ultimately live through all the ages of life—the child who begets the man, the child who is the father of the man.

There is a second interpretation. When you have a child of your own, be it your true offspring or a child in the context of the symbolism of this afternoon, what you amass in your own lifetime becomes integral to the core of that child's life. But the child's ultimate depth of knowledge encompasses not only this parental bequest, but the continued lifetime of growth and maturation that will be his or hers to experience. In that context, he will become an individual of overall greater magnitude than the parent. Thus, in reverse chronologic sequence, but nonetheless substantively correct, the child is father of the man.

It is in that sense of wanting to impart some special thoughts to you at this stage of your lives, but well aware of the unique contributions that each of you will make, that I share these personal reflections with you. First and

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NOEL I. ROBIN, M.D., physician-in-chief, The Stamford Hospital, professor of medicine and associate dean, New York Medical College. Address delivered 8 September 1997.

foremost, I would like to say that medicine was, is, and forever will be the most glorious, fulfilling, and enchanting of professions. You are, indeed, very fortunate human beings to be here today. This in no way is meant to minimize the worth of others, the individual and collective significance of their work, and the satisfaction and self-esteem that each of us can obtain from commitment and pursuit. It is only to say that medicine, as a unique profession, affords one the ability to deal with the most fundamental issues of the human condition—of health, sustenance, and indeed, of life, itself. And, it is also able to perform this in a manner that is individualized, personalized, and humanized. It is a science that seeks exactness and perfection and a science that utilizes the information and knowledge of all scientific disciplines that have been gleaned over the years. Yet, above all, medicine must integrate that science in a manner that is meaningful and relevant to the human condition. Medicine is ultimately an art. As a profession, medicine has no equal.

But medicine cannot be practiced in a vacuum; we indeed live in a very real world. It is a world of continuous and inexorable change, a world that paradoxically reflects change in such a tumultuous way that the patterns and precepts relevant to one generation can seem antiquated and irrelevant to the next. Yet, this is also a world of order and law because life and society are subject to fundamental universal laws. Indeed, the very process of change, itself, is governed by law.

The most overt global change we are witnessing is a redefining and structuring of a world economic order. For the inherent good, bad, and indifferent that can be inferred from this order, it has resulted in the production of worldwide commodities and services that have defied Malthusian predictions; it is an order that has resulted in the incredible transformation of former third world colonies into formidable economic powers and also represents a beacon of hope for presently languishing societies. It is an order that fairly peacefully dismantled the Soviet Empire and an order that has given the world the semblance of solace that at least the stable industrialized and technologized nations will not again engage in open warfare with one another, that the biblical prophecy that "they shall turn their swords into plowshares and their spears into pruning hooks" is no more an unreachable goal.

But this economic order affects us in other ways as well. And surely, in our day-to-day lives, and in the very practice of medicine, change is upon us. Indeed, if we do not change, we are not congruent with the rest of the world. Does it alter the manner in which medicine is practiced, the actual patterns of care and the manner in which service is provided? Yes, undeniably! Does this change alter the intrinsic value of medicine, its honorable precepts, and its indivisible values? No; never! Can the basic tenets of medicine and the role of the physician as we idealize him or her be reconciled with the pragmatism of contemporary economics and its preoccupation with the growth and power of its constituent players? Yes, I believe so. But its reconciliation requires an understanding of this change on the part of physicians and the medical profession and indeed, a proactive and anticipatory approach to change. For some of what is change today will soon become tomorrow's status quo, that will itself be subject to future revision and alteration. But more than that, what is required of physicians is that they never stray from the ideals that first brought them to their profession. The role of the physician is that of a healer, of an advocate for his or her patients. While physicians must practice their art with prudence and wisdom within the reality of the medical care infrastructure, their decisions must neither be restrained nor constrained by external and ulterior corporate motives. They are never to be providers and their patients are never to be customers. A physician must always and forever be … a physician.

I want to speak of what a wonderful and supportive profession medicine is and must always be. Only a physician can truly understand the making of a doctor. Medicine is a profession of hard work, discipline, and emotional stress. You need each other's help and camaraderie. You will require that help in the clinical environment when the complexities of case management will necessitate the skills and knowledge of many. You will need it, and find it, in the sharing of information and insights, in the discussion of intriguing and challenging cases, in the insights and revelations that will come from your continued self-education, from your participation in professional societies and organizations, and in your personal contributions to the burgeoning well of knowledge. Look around you at all your colleagues. You see others with whom you will work and bond throughout your formal medical education. Circumstances of life and profession will probably dictate that after you graduate, most of these colleagues will be seen with frugal frequency. I can assure you, however, that when you do encounter one another in the future, your conversations will resume with scarcely a beat being lost, and that same intangible essence that once brought you so close to one another will be in demonstrable abundance.

I also want to tell you the importance of humility. Medicine may have its indivisible virtues and glorious qualities but that does not grant its practitioners the right to indifferent arrogance or insensitive hubris. Don't forget where you've come from in this world and where you are going. Another of my favorite poems is "Ozymandias," in which Shelley describes a mythical monarch who on a statue erected to his immortality proclaims that, "My name is Ozymandias, king of kings: Look on my works, ye Mighty, and despair!" All that remained of that forgotten monument, discovered by chance by a "traveller from an antique land" is a heap of rubble. The poem ends: "Round the decay of that colossal wreck, boundless and bare the lone and level sands stretch far away." Remember that we are all products of our past, and as such are here as a result of the achievements and sacrifices of others. It is said that Johannes Brahms waited 20 years before finally revealing his glorious first symphony to an awaiting world, because he heard the heavy footsteps of Beethoven trodding behind him. Would there be an Einstein without the enlightenment of Newtonian physics? Could a Frank Lloyd Wright have been so creative without the development of the Roman arch two thousand years before? How many great contemporary works of literature use fundamental themes that are integral to the writings of Homer, Aeschylus, and Sophocles? Are not the most advanced imaging technologies in medicine beholden to principles of particulate matter and quantum mechanics? And do we not owe much to the benefactors of our profession, though not physicians themselves, who saw to it that research and investigative endeavors would be fostered: John D. Rockefeller, Charles Kettering, and Robert Wood Johnson, among others. And on a very personal level, are we not indebted to our parents and other loved ones who have seen to it that our visions and aspirations would be fulfilled, many such parents and their parents having come from distant lands to these blessed shores in the quest of such opportunity.

The commitment and responsibilities of your profession notwithstanding, the many hours of dedication and hard work that await you, I must remind you at the same time of the importance of a balanced life. You will need this both to sustain you throughout your long career, and for your own physical and mental well-being. A balanced life will make you a better physician because you will be able to give medicine an uncompromised intensity and focused commitment. You will appreciate how cherished other moments can be that define you as a person and allow you to partake of the world around you. You will also be living by the tenets you promulgate to your patients as you seek to sustain their health and quality of life. But use your time well and make moments count. Give short shrift to time wasters and exploiters. Enjoy the treasures of earth and its wonderment, in the glorious heritage of its diverse cultures and civilizations, past and present. Partake of the priceless legacy that creative minds have bequeathed. Do not let your life pass without hearing the music of Bach, Sibelius, and Ellington; without reading the writings of Marcus Aurelius, Robert Frost, and Toni Morrison; do not travel to any city without visiting its museums. Bask in the very majesty of creation itself—in rivers, mountains, and in the diversity of nature. Make your family indispensably vital to your fulfillment as a human being. And yes, exalt in the most personalized and meaningful creation of all—in your own children. They are your heritage. Give them not only your love, but also give them your time. The years are precious and they are ever so fleeting.

And now, after telling you how important it is to fulfill your potential as a total human being, I must also tell you that medicine is a lifetime of learning. This is not meant to discourage or frustrate you, because the act of learning can be a pleasurable and even exhilarating process. Continued learning enables you to develop insights and achieve levels of understanding previously unattainable. An educated mind also requires ongoing challenge and stimulation much as athletic musculature requires repeated physical exercise. But while there is empiricism and pragmatism to medical knowledge, medicine also has a very important infrastructure. These formative years you are embarking upon are vital to your understanding of that infrastructure. The better versed you are in the fundamental principles of basic human design and their pathologic derangements, the better prepared you will be to incorporate newly acquired knowledge into a meaningful continuum. No matter how specific therapeutic approaches to diabetes may become, the underlying issues of intermediary metabolism and hormonal action will remain inviolable. Drugs and procedures that alter the management of congestive cardiomyopathy will invariably change, but the universality of Laplace's law will forever dictate the dynamic parameters that will determine their effectiveness. Continuing evolution notwithstanding, fundamental human anatomy and physiology will remain as in the past.

And so, my younger colleagues, I leave you with these reflections and thoughts and I let you return to your many tasks, to embark upon this new stage in the fulfillment of your life's quest and indeed, to behold your own "rainbow in the sky." May challenges forever await you and may you meet these challenges with enthusiasm and delight. And, at all times, in all places, in some ways overt and in so many other ways subtle and elusive, may you find a lifetime of fulfillment and inexhaustible enchantment in this most wondrous of professions.

Guest Editorial

Assistance with Suicide

It is my belief that both sides in this debate on whether physician-assisted suicide (PAS) should be made legal are well intentioned. It is also my belief that, however well-intentioned, the effort to legalize PAS is a vain effort to legislate away the existence of pain and discomfort. Though the goal is a laudable one, I oppose this particular means of achieving it—from an ethical, professional, and practical perspective.

It may be true that the medical profession does not always show sufficient concern for the pain and suffering that their patients may experience, especially those in the throes of a painful death. It is true that we need to do more, and more is being done. The hospice movement is growing and deserves further support. Medical education is emphasizing the ethics of what we do and addressing the appropriate care of dying patients (see this issue pp 139-42). Many institutions are addressing how to do a better job of giving patients more autonomy and choice while emphasizing adequate pain control. When medications are used appropriately they can control almost any degree of pain. I am comfortable knowing that a medication I give to a terminally ill patient to control her physical pain may result in her dying sooner than she might otherwise have, though my *intention* is to relieve physical pain, not to kill the patient. It is ethically justifiable to take dying patients off life support while ensuring their comfort. I see a clear distinction between letting the natural process of dying take its own course and the active taking of a patient's life by medical means.

Human existence has the potential, if not the certainty, sometimes to be painful, the pain of terminal bone cancer, the pain of a loved one's unexpected death, the pain of hunger, the pain of discrimination, the pain of mental illness, all are a part of life.

There is physical pain, psychological pain, and social pain. To be told that you have an illness that will over time result in disability and may ultimately result in your death has to be a painful experience. It may be even more painful for someone to be told that his youngest child was killed in a car accident, or that he is infertile, or that because of his sexual orientation he is rejected by his family. These painful experiences may not result in death and are not terminal illnesses, but life is a terminal condition, and many forms of illness, and not only physical ones, can result in death. The solution to pain, be it physical or otherwise, is not to kill people or assist them to end their own lives. The solution is to provide comfort and, to the best of our ability, relieve pain, where and when we can. I will never be able to "doctor away" all my patient's pains and troubles and, with due respect, our lawmakers will never be able to legislate them all away.

It is often difficult for physicians to be sure that an illness has entered its terminal stage. We are reluctant to tell a patient that she will die within a certain period of time, since we are so often wrong. Many patients in hospice care do not die within the Medicare limit for hospice coverage and may even end up coming off hospice care. Often by the time a physician is certain that a patient's time of death is approaching, death is imminent, and occurs within less time than the waiting period prescribed by proposed assisted suicide statutes. Physicians have great difficulty separating patient's physical pain from their psychological pain. They have great difficulty distinguishing between a patient's resignation and understandable sadness at the prospect of dying and the presence of clinical depression. No matter how many safeguards are put in place, the vulnerable of our society will be at much greater risk under a PAS law, a law that may act against their better interest, not just because they are vulnerable, but because their pain and depression have been neglected and they can no longer make rational decisions.

I urge legislators to reject legalizing physician assisted suicide in the state of Connecticut. I urge doctors instead to continue their best efforts to decrease pain and suffering where and when they can, and to tell their legislators not to burden them with a license to kill.

Patrick P. Coll, M.D.
Associate Professor, Family Medicine and Medicine,
Associate Director, Center on Aging,
University of Connecticut School of Medicine

50 Years Ago

From *The Connecticut State Medical Journal*

March 1948

Medical Practice Group

CONNECTICUT'S first full scale medical practice group has been organized by six New Britain physicians.

Members of the group include Donald A. Bristoll, obstetrics and gynecology; Bliss B. Clark, surgery; Louis W. Daley, otolaryngology; George P. Perakos, internal medicine and gastro-enterology; John C. White, internal medicine and cardiology; and Dwight E. Wilson, urology.

The associates are all members of the staff at New Britain General Hospital, and each holds appointment as a chief of service or as a senior in his specialty. They are all certified by their respective specialty boards.

Their practice group was formed only after months spent in studying the development of similar groups in other sections of the country, and gauging the possibilities of success in a typical New England community.

The group is located in a growing industrial city of 80,000 population, the center of a hospital area which serves an estimated 120,000 people. It is housed in a large estate-type home at 32 Grove Hill, once the residence of Mrs. Florence Gates Judd.

The residence has been modified to meet the needs of the group, but this has not been carried to the point of sacrificing the homelike appearance of the interior. Patients appreciate this atmosphere of informality, as has already been evidenced by many expressions of approval. The property is situated a short distance from a busy thoroughfare, near the center of the city. Though removed from downtown traffic and noise, it is readily accessible by automobile and three bus routes. The parking problem has been solved for patients of the group by provision of adequate space on and adjacent to the grounds.

In response to an inquiry from the STATE MEDICAL JOURNAL, members of the group have told how their group was organized and why, after prolonged study, they decided upon group practice. Their motivations they describe as chiefly two, a conviction that local medical groups can meet in large measure the increasing challenge of government medicine, and a belief that the consolidation of medical practice and facilities at the point of patient contact can produce more efficient medical care at lower costs.

The group has been in existence for only eight months, and its members modestly caution that they cannot present conclusions based on long experience. Yet the problems inherent in bringing together physicians who have been practicing independently, and the means by which they have modified their individual interests to the advantage of the group are matters which have brought many queries from other physicians.

One of the advantages claimed for group practice, the convenience to the patient of having consultant services readily available, has already been demonstrated. At a time when patients are outspokenly concerned over the delays and inconveniences of arranging visits with consulting physicians, the group has found that informal and spontaneous conferences on problems of diagnosis have been frequent and useful.

The advantage of a better distribution of time between office hours and personal pursuits promises early realization for group physicians. Doctors who practice independently are often so tied down by professional responsibilities that it is difficult to arrange adequate time for vacations, postgraduate study, and attendance at medical meetings. Group members explain that the extent to which this disadvantage can be corrected is a subject of current planning.

Plans are also being developed to secure other advantages, such as employment of technical assistants for laboratory and x-ray work, formation of an administrative staff, and the maintenance of a uniform system of clinical records. The clinical record system will provide a complete history and physical record for each patient. These will be maintained in a central file, where they will be readily available to any physician in the group, thus obviating any necessity for duplicate records.

Reprinted from the *Connecticut State Medical Journal*, March 1948.

The group hopes in due time to demonstrate that it can provide security for its members against loss from illness, or from absence for the purpose of study, and smooth out some of the inequalities of income which physicians generally experience throughout years of professional activity. A retirement income plan is also being outlined.

The New Britain Medical Group evolved slowly after months of weekly and sometimes semi-weekly discussions. In the course of these discussions a number of seemingly insurmountable problems developed. But in the final organization of the group the difficulties disappeared when it became evident to all its members that each believed implicitly in the integrity of the others, and that unselfish attitudes predominated. Group members emphasize that these qualities are fundamental for the organization of any group. They point out that it took months of discussions and self-education to construct the necessary foundation of mutual agreement.

That medicine is not alone in its concern to provide adequate medical care was illustrated during the formation of the group. The technique of organizing became the sole responsibility of a young attorney in the community, and his enthusiasm awakened the interest of his two partners. Soon all three were engaged in a lengthy study of group medical practice. They contacted other groups throughout the country by letter and telephone, talked to group consultants, acquired information from the American Medical Association, the Connecticut State Medical Society, and other medical organizations. Considerable time was spent with a firm of accountants in Hartford, and here one of the senior partners became so concerned with the problems involved that he produced for the group a valuable store of information regarding sound business organization.

At the conclusion of the study it was the opinion of the attorneys that the group property, including equipment as well as buildings, should be owned by a corporation. The doctors themselves were organized as a limited partnership, and the partnership agreement provides for almost any problem that may arise in the foreseeable future. Division of income among the partners is described in the agreement which also provides for maintenance of salaries during vacations, periods of illness, and visits to clinics for purposes of study. Funds are to be set aside for retirement, life insurance, and future expansion.

The agreement also provides for the admission of new partners, and voluntary or requested separation. Purchase of equipment, the hiring of professional assistants and non professional personnel, business operation and accounting procedures, relations with associated enterprises, ownership of the reserve funds, voting privileges, and policies of management are additional matters set forth in the partnership agreement.

The introduction of group practice has provoked considerable comment among the other physicians in the community. There has been some apprehension that it might disturb the familiar patterns of practice. But group members believe that the practice of other physicians has not been adversely affected. They feel that since the group is composed of specialists, it is to their interest to maintain good relationships, especially in the matter of referring patients back to their family physicians following consultations or operative procedures. Plans for the growth of the group are expected to provide other branches of the medical specialties and are unlikely to invade the field of the family physician. It is pointed out, however, that no expansion will be undertaken until the present group has been in existence long enough to assure completely smooth operation.

Physicians of the group feel that the soundest advice which they received during their period of organization came from one of their attorneys:

"I have no doubt that each of you at some time during the past eight months has had misgivings and doubts regarding the value of the group and your participation in it. During the hectic formative period such a reaction would be normal, but it should have been just as normal to determine that this group had substance enough to realize its objectives.

"Early in the discussion periods it was once contended that the group had more to offer than benefit to the men comprising it; that the people of this and surrounding communities might be more adequately serviced; that the standard of practice might be raised; that an effective measure of combating localized medicine might be created; that an institution might be founded which, over a period of years, would allow the establishment of charitable and scholastic funds.

"These factors cannot be ignored because they, and not personal or group benefit, will be the basis for the growth and continuing success of the group. The possibility of failure is remote. Disintegration could occur only because of internal conflict and dissension. It would be astute business to keep the broader aspects and possibilities of this group constantly in mind when discussing problems which will arise."

Evaluation and Management Coding

In 1992 the American Medical Association participated in the development of new evaluation and management (E/M) codes formatted for inclusion in the physicians' Current Procedural Terminology handbook. The impetus for the recoding was provided by the Health Care Financing Administration's adoption of the RBRVS for services reimbursement, and as an alternative to appropriate proposals offered by others. It had been suggested, for instance, that E/M code levels be based solely on time rather than reflecting the clinical content of the service rendered. Recall that at this particular time HCFA was routinely down-coding physician reimbursement claims utilizing the older coding system. This recoding initiative was reviewed and approved by nearly all national medical specialty societies as part of their participation in the CPT Editorial Panel process.

At this point the Federal Office of Management and Budget (OMB) mandated that HCFA adopt documentation guidelines for the new E/M codes. Extensive negotiations led to initial acceptable, albeit with reservations, documentation guidelines by the AMA, national specialty societies, and HCFA.

Concerns with the documentation guidelines have always existed but have recently been exacerbated by concerns from state and specialty societies that minor documentation problems not trigger Medicare fraud and abuse sanctions. This latter concern is heightened by the results of a Fiscal Year 1996 Financial Audit by the Office of the Inspector General that concluded, correctly or not, that a large portion of the Medicare services audited did not contain adequate documentation and that as a result more than 23 billion dollars had been spent inappropriately. Many are concerned that conclusions such as the one foregoing have the potential to vastly broaden the definition of what constitutes fraud and abuse. As a result of the audit it can be expected that HCFA will place even greater emphasis on the need for adequate documentation and Medicare carriers will likely be using these guidelines in helping them to determine or verify that the reported services were actually rendered. HCFA will no doubt be emboldened in its stance on these issues by recent revelations of institutional irregularities resulting in the imposition of truly staggering penalties and the subsequent settlements achieved.

Nevertheless, the dissastisfaction with the proposed documentation guidelines for and by physicians is real and growing as physicians' awareness grows. The executive vice president of the California Medical Association has been reported as saying that the guidelines act as an unwelcome barrier to the patient-physician relationship, raise the cost of health care, and potentially decrease Medicare patients' access to care. It would appear for example that relevant or not, physicians must perform and document all elements as specified in the instructions for each organ system examination. The increased administrative burden, the examination requirements, coupled with the multiple steps required under CPT to select an appropriate level of history and medical decision-making, make selecting an appropriate service code an arduous and highly complex process prone to error. Instead of fostering a more supportive system affording a physician more flexibility and a greater opportunity to focus on the patients' health problems, the guidelines force physicians to focus their energies on documenting many, perhaps insignificant, examination components in order to ensure compliance with Medicare billing rules.

HCFA has agreed to delay implementation of these guidelines until 1 July 1998 and further delays may be obtained.

AMA has enlisted the support of the Practicing Physicians Advisory Council (PPAC) in serving as a resource to HCFA for obtaining the views of the practicing physician community. We should also encourage an increased role, as mandated by Congress, in PPAC's relationship to HCFA.

The six-month implementation delay allows us an opportunity to address the concerns expressed from all sides of our physician federation. We all believe that good documentation is an essential component of medical practice. An appropriately documented medical record should serve to facilitate claims processing and support care provided as a legal document should that be found necessary.

The AMA is determined to implement corrective action in consort with our national specialty societies in reducing the excessive documentation currently contained in the Evaluation and Management Guidelines. There will be efforts made to suspend implementation of single system evaluation guidelines pending national medical specialty society approval. We will work with HCFA to establish a test period in a specific geographic region for evaluation of the effect these new guidelines may have on quality of patient care, cost effectiveness, and efficiency of delivery prior to nationwide implementation.

Finally, be assured that AMA is committed to working with all of us to insure that physicians are sufficiently apprised of CPT coding for Evaluation and Management Services and carrier review criteria with ample time afforded for education and implementation. A California Medical Society sponsored survey found that 30% of its membership was not aware that guidelines even existed, never mind the brouhaha over implementation. Ignorance is not bliss.

Stanley J. Keating, Jr., M.D.
President

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Hermann Helmholtz: From Army Surgeon to Physicist

ROBERT U. MASSEY, M.D.

IN 1944 I bought a second-hand ophthalmoscope for my course in physical diagnosis. I still have it, it works beautifully, and is the only one I have ever owned. Dr. Gordon Myers, head of the department of medicine, taught the entire course in physical diagnosis (this was wartime and more than half the faculty were away), devoting the first two weeks to ophthalmoscopy. He mentioned that this elegant diagnostic tool had been invented by Helmholtz. I was fascinated by how with the aid of this little system of lenses and a bright beam of light one could actually look inside the body, or at least a small part of it, see the retina with its venules and arterioles, the optic nerve head, the macula—one retina looking directly at another!

Hermann Ludwig Ferdinand von Helmholtz (1821–94) was one of that outstanding crowd of German physicians in the 19th century that made Germany for a time the center of medical science. He was born at Potsdam in 1821, and by the age of 12 was reading both Arabic and Greek. His true interest was physics, but his father, a teacher, said he could not afford the university and urged his son to enlist in the army and attend the Friedrich-Wilhelm Institut in Berlin to become an army surgeon. By great good fortune he was able to pursue his clinical studies at the University of Berlin under Johannes Müller, whose distinguished students were to include the likes of Schwann, Henle, du Bois-Reymond, and Virchow.

In his doctoral thesis in 1842 he described his work on the nervous systems of invertebrates and demonstrated the relationship between nerve cells and the nerve fibers themselves. After a short time in the barracks at Potsdam, his genius was recognized and he was appointed associate professor of physiology at the University. At heart he remained a physicist convinced that life itself was no more than physical chemistry, and his first experimental work was to prove that muscular movement was the result of chemical activity and the major source of animal heat. In 1847 he wrote one of the seminal scientific papers of the 19th century, "Über die Erhaltung der Kraft" (On the Conservation of Energy), proving mathematically and experimentally that light, heat, electricity, and chemical energy can neither be created *de novo* nor destroyed, but are all transformable from one to another without in the least being diminished, the first law of thermodynamics, just as we learned in general science! Robert Mayer and others had earlier postulated something of the same notion, but failed to produce the necessary mathematical and experimental proofs.

Three years later, by now at the University of Königsberg, he was able to measure the velocity of the motor nerve impulse, something that Müller had said could never be done. In 1851, in trying to explain to his students the retinal reflex, he put together an ophthalmoscope, and for the first time could actually see the fundus from whence that image arose. He designed other optical instruments as well and began an intensive study of vision culminating in the publication of his text, *Handbuch der physiologischen Optik.* His studies of color perception persuaded him that colors perceived depend upon responses in the retina and visual cortex and do not inhere in the objects themselves. The primary colors that we see he said are red, green, and violet (or blue)—just as we learned from our Best and Taylor's years ago—the Young-Helmholtz theory! His beloved teacher, Johannes Müller had encouraged his interest in color vision, an interest that Müller in turn had inherited from his hero Goethe whose scientific studies, while not always confirmable, had set him apart from the romantic nature philosophy then so in vogue in Western Europe.

His next field to conquer was that of sound. He coined the term *Tonatom,* or tone atom, meaning the most discrete tone the ear can distinguish and cannot further resolve by subdividing it. From these studies of the physiology of hearing he wrote another major work, "On the Sensation of Tone as a Physiologic Basis for the Theory of Music,"

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

stimulating Debussy's speculations on overtones, consonances, and dissonances.

By 1871 he had proved his mastery of this preeminent science and was called to Berlin as professor of physics. He later remarked (1877) "Medicine was once the intellectual home in which I grew up; and even the immigrant best understands and is best understood by his native land." From then until his death in 1894 he remained the physician immigrant in the land of the physical sciences. The Yale professor Willard Gibbs was one of his students, as also was H. R. Hertz whose name attaches to the unit of frequency of the radio waves that he discovered in Helmholtz's laboratory. With Gibbs and others he elaborated upon the second law of thermodynamics, formulated earlier by Clausius and Lord Kelvin, in his words, "... the theory of thermal death ... the universe would run down to a state of uniform temperature and be condemned to a state of eternal rest."

He distinguished between empirical (a posteriori) science and pure (a priori) science. Even though his respected Johannes Müller retained something of vitalism in his thinking about physiology, Helmholtz rejected all but physics and chemistry, absolute reductionism, even claiming that life itself, rather than being a very local exception to the principle of entropy, would in fact be shown to be an example of it! He is considered to be one of the founders of logical positivism, along with Comte, Mach, Hertz, Boltzmann, and Poincaré. He rejected entirely the almost mystical natural philosophy of the early years of the late 18th and early 19th century, proposing instead such concepts as psychophysics and physiological psychology, but worried nonetheless about a too unbridled philosophic materialism: "Our generation has continued to suffer from the thralldom of spiritualist metaphysics. The younger generation will doubtless have to protect itself against the thralldom of materialist metaphysics."

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This Month's Reading in Review

TIMOTHY B. NORBECK

"But medical decisions should be made by medical doctors, not insurance company accountants. You have the right to know all your medical options, not just the cheapest. You have the right to choose the doctor you want for the care you need. You have the right to emergency room care, wherever and whenever you need it. You have the right to keep your medical records confidential."

President Clinton, in his January 27th
State of the Union Message.

EDITOR'S NOTE: Interestingly enough, in reporting excerpts of the President's speech, the *Hartford Courant* left out the first sentence above. *The New York Times* reported it verbatim.

"One of the loudest and most spontaneous applause lines in the speech came when the president took a shot at managed care as it is done now.... Audiences all over the country were cheering it. Here the president is saying he is going to fix that."

CNN's Jeff Greenfield in discussing
President Clinton's reference to managed care.
(27 January 1998)

"A statewide survey commissioned by California Governor Pete Wilson has discovered that 42% of Californians surveyed have had a problem with their health plan in the past year."

LACMA Physician (January 1998)

Can't Possibly Be True—In December, John Caballero, 42, who had just been awarded $30 million in punitive damages by a jury in Corpus Christi, Texas, in his lawsuit over injuries from an oil well explosion, voluntarily gave up every penny of it when the company agreed to institute a safety plan to protect future workers. (Caballero will retain several million dollars in actual damages for treatment of broken vertebrae, a crushed foot and ankle, a dislocated hip, vision and hearing loss, and a scarring of the scalp.)

News of the Weird (6 February 1998)

A new Kaiser Family Foundation study shows that media coverage of managed care is mostly neutral and not biased against managed care as many in the industry have charged.... The survey found that "64% of the stories in daily newspapers, magazines and TV network news programs from 1990 to 1997 were neutral in tone." One quarter were critical of managed care, while 11% praised the industry.

Los Angeles Times (22 January 1998)

"But for now, the HMO industry is struggling. At least half of the nation's 650 HMOs will lose money in 1997... Less than 60% of consumers are highly satisfied with their HMO, according to a recent nationwide survey of 130,000 HMO enrollees.... Another poll found that 44% of HMO members feared they wouldn't get the care they needed if they fell seriously ill.

'This industry has a significant image problem,' says Robert Blendon, a professor of health policy at Harvard University. 'The public perceives that HMOs are much more interested in saving money than delivering the best quality of care. They don't see the pluses at all.'"

USA Today (27 December 1997)

Look On The Bright Side: "Outside of the killings, Washington, D.C. has one of the lowest crime rates in the country."

Washington, D.C. Mayor Marion Barry
Executive Newsletter (February 1998)

AFL-CIO President John J. Sweeney said that the union will lobby Congress and the White House this year for better health-care coverage for workers, expanded pension programs, wage equality for women, a higher minimum wage and federal laws to make union recruiting easier.... The agenda is based on the issues identified by workers in a survey it commissioned by Peter D. Hart Research Associates.... Surveyed union members said their top concern was pensions being cut; nonunion respondents were most concerned about HMO limitations on their choice of doctors.

Wall Street Journal (27 January 1998)

Only in America: In Springfield, Mo., in June, Vernon Wayne Richmond, 18, stood up in court to give the details of his crime as part of a plea bargain to cocaine possession. Richmond said he found cocaine, put it in his pocket, and then was arrested by police after a Wal-Mart guard detained him. Unfortunately for him, Richmond had misunderstood which of his cases the plea was for. Actually, the district attorney was prosecuting him for an earlier arrest for having cocaine in his car and was unaware of the Wal-Mart arrest.

Internet (31 December 1997)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

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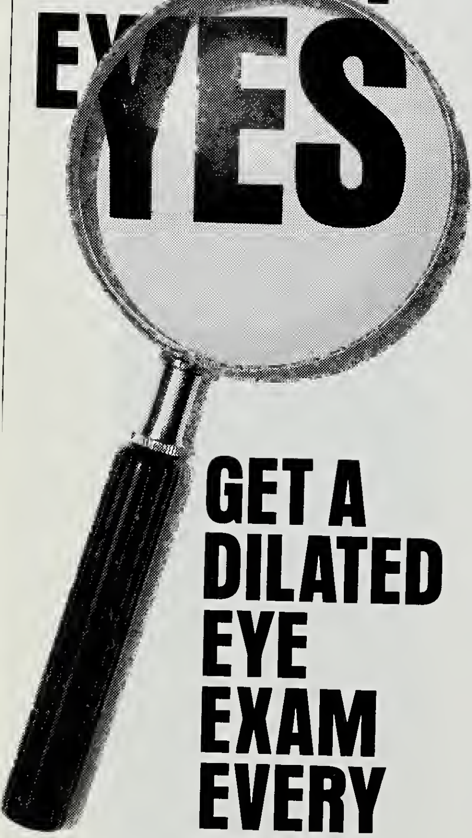

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

In Response to Connecticut College of Emergency Physicians' Abstract by Drs. Daly and Reiser

Letter to the Editor: I am writing in response to the abstract published by Devin P. Daly and Robert C. Reiser, M.D., M.S., "Anterior Glenohumeral Dislocations in the Emergency Department: Do Prereduction Radiographic Findings Influence Patient Management?," *Connecticut Medicine* November 1997. I had no sooner finished reading this abstract, which suggests the elimination of prereduction radiographs for anterior shoulder dislocations, when into my office that very morning came a 14-year-old boy treated in such a fashion three days earlier. He had suffered a skiing injury and had not received prereduction radiographs. His history and physical findings were suggestive of anterior shoulder dislocation and he was manipulated based on clinical diagnosis. In point of fact he had a displaced Salter II fracture of the proximal humerus.

The authors suggest in their conclusion that prereduction radiographs do not alter emergency department management of anterior shoulder dislocations. They go on to suggest cost and patient suffering will also be reduced. While this may be the case for certain injuries where recent protocols have been established for ankle injuries, I cannot think of any protocols other than the ones suggested by the authors that call for manipulation of a major bone or joint injury without appropriate radiographs at hand. I hope that this example highlights the need to set aside "efficiency" when it does not result in better patient outcome or appropriate care.

John M. Keggi, M.D.
Orthopaedic Surgeon
Waterbury

Kevin P. Daly and Robert C. Reiser, M.D. respond: Dr. Keggi's comments are very much appreciated. I wholeheartedly agree that we should set aside "efficiency" when it does not result in a better patient outcome. Based on the results of our retrospective study we concluded that prereduction radiographs *rarely* alter the management of patients with anterior should dislocations in the emergency department. Although we did not find any patient where management was influenced, at this point we cannot recommend a protocol to determine which patients do not need prereduction radiographs. We are in no way suggesting that we should completely eliminate prereduction radiographs. We do believe that, with further prospective studies, the data will support the elimination of routine prereduction radiographs for a subgroup of patients that present with anterior shoulder dislocations in the emergency department. These patients will likely be adults ≤45 years of age with an atraumatic recurrent dislocation. At least 27% of the patients in our study were in this category. We also believe that with a larger study we will find subgroups of patients where obtaining prereduction radiographs will be supported by the data. These patients will likely be the elderly, significant traumas, and children. The case Dr. Keggi describes exemplifies the special risks for children with open growth plates. We failed to mention in the abstract that there were very few children in our study. There were no patients under 15 years of age and only 19 patients under 18 years of age.

We believe that it is important to investigate how we care for patients to determine whether it is supported by hard data. It is just as important not to prematurely recommend changes in clinical practice without adequate data to support that change. Your example illustrates that further study is needed before a protocol can be developed for which we all can have 100% confidence.

Kevin P. Daly,
Medical student, Yale University School of Medicine
Robert C. Reiser, M.D., M.S., F.A.C.E.P.,
Assistant Professor of Emergency Medicine,
University of Virginia

In Response to "Outbreak of Staphylococcal Food Poisoning Associated with Precooked Ham—Florida, 1997"

Letter to the Editor: The article in the January 1998 issue of *Connecticut Medicine on* "Outbreak of Staphylococcal Food Poisoning Associated with Precooked Ham—Florida, 1997" reminded me of an incident in 1944 in Camp Patrick Henry, Virginia, a staging area for the North Africa invasion. I was Chief of the Laboratory Service in the Station Hospital when the camp was filled with paratroopers. That evening, they were served ham which had previously been cooked in large pans. A short time after dinner, they were admitted to the hospital with vomiting, diarrhea, and dehydration at a rate faster than London's hospitals had experienced during the blitz. Fortunately, it was a nearly empty 2,000 bed hospital. We were all pressed into service relieving dehydration with clysis. As I approached one bed, the occupant climbed to the foot of the bed to vomit into a container on the floor. As he did so, he must have been seized with a severe abdominal spasm, because a stream of fecal material left his rear end and covered the distance to the next bed. I had seen projectile vomiting, but never projectile diarrhea before. The following morning, they were all put aboard ship and on their way.

As Sanitary Officer, it was my duty to investigate. Of course, we grew Staph from the ham and from the vomitus. What had happened was that the pans of ham had been removed from the oven and placed on the floor, which had recently been mopped. The pans were then stacked on top of one another so that drippings from the wet floor could contaminate the contents of the pans.

Raymond Yesner, M.D.
Professor of Pathology Emeritus,
Senior Research Scientist
Yale University School of Medicine
New Haven

Remembering Wilder Penfield

"Keep the businessmen out of medicine!," said Wilder Penfield. I strongly repeated Penfield's admonition at the recent Harvard conference on "Professionalism and Ethics in Managed Care," just as I did in my letter to the editor of the *New England Journal of Medicine* (1 January 1998). I've received warm responses from physicians across the U.S.A. because of my letter, which *NEJM* dubbed "Professionalism."

Now these businessmen are all over medicine, inside and out, taking their enormous profits, denying our patients, defining us, what we may do, when we may do it, even what we say. The profiteers have destroyed the bonds of trust, and we sleeping physicians have permitted this disaster. Is my physician serving me? Or himself? Or the insurance carrier? Is he really *my* physician? Why does he give me no time? Does he care?

As a young neurosurgical resident I vividly remember Wilder Penfield: tall, white-haired, vigorous, coming in from the freezing cold for early rounds, his old Studerbaker parked in front of the Montreal Neurological Institute. I'd already read his books in medical school, and as a general surgeon in the U.S.A.F. He was the best clinical neuroscientist I've ever known. His books told the story of epilepsy and the living human brain, alert, remembering, and speaking, its pulsating cortex exposed to his stimulating electrode in the operating theaters of the MNI. Phanor Perot and I called our beloved Chief to the OR as our stimulating electrode danced on the right temporal cortex of a French Canadian patient who suffered uncontrolled convulsions. The melody stopped on withdrawal of the electrode, to start once again as it touched the surface of his brain, exciting a neuronal circuit of long ago. "Astounding!" said Wilder, listening to the cerebral song evoked from the very infancy of our patient, now a frightened man 30 years later with his cranium open to countless photons of OR lights, and his cortex to the searching flow of our electrons. Our patient was no "health care consumer." We were physicians, not "health care providers." We were certain, absolutely, of our bond of trust.

Penfield had a genius for getting right to the bottom of things, into human memory and the hippocampus, into neurocytology, and even philosophy. He studied with the great ones, Sherrington, Cajal, Cushing, to name a few. Penfield was a purifier. Had he lived a few centuries earlier, he would have driven the alchemists out of medicine by forcibly elevating medicine from its medieval pit. I remember the bright light of his intellect shining on the deepest nature of man.

Christ was a purifier too, driving money changers from the temple. Now we have let them in, to our disgrace. Once we were Knights, duty bound to protect each and every patient, a sacred trust, an unspoken honor which had nothing to do with money. It was a contract of the heart. We forget at our peril.

Charles W. Needham, M.D., F.A.C.S.
Norwalk

Professional Vacuum

Letter to the Editor: This is in regards to the proposal to the Public Health Committee that Advanced Nurse Practitioners be allowed to practice independently.

I have had over 30 years of experience in medicine working with nurse practitioners. Professional relationships have been positive as have the outcomes for patients.

Advanced Nurse Practitioners have M.S. degrees and have worked with M.D.s for their practicums. Such nurses cannot work in a professional vacuum any more than can we be entirely independent of specialists.

Physicians have worked with nurses at all levels of practice and I am sure that this custom will persist in the future. By encouraging further training and increased activity for nurses we will increase the benefits and spectrum of health care for our growing population.

May I suggest that our Society reconsider its stand in this matter.

Lamson Blaney, M.D.
Mansfield Center

The Misnomer "Physician Assisted Living"

Letter to the Editor: I applaud the December issue of *Connecticut Medicine* highlighting the hospice system in our state. It is important to inform and educate the public and our profession regarding end-of-life issues and the Principles of Hospice Care.

The array of luminaries that you have enlisted to enthuse over Physician Assisted Living gives me pause as I write to criticize the very title of your initiative.

Hospice is concerned with dying, a part of life and one heretofore given short shrift by many in our profession. Although physicians are essential to the hospice program the dying person communicates and depends most often on other caregivers along with family.

The misnomer "Physician Assisted Living" gives undeserved prominence to the doctor part of hospice while not including those who do the major part of caring. More importantly, by not expressing that hospice is about dying, the title obfuscates and denies a prime medical ethic, that of truth telling. It is time to stop the euphemistic language and present this serious subject without the hypocritical title.

Philip I. Kotch, M.D.
Newtown

Rosemary Hürzeler Johnson, R.N., M.P.H., H.A., President and CEO, The Connecticut Hospice, Inc., responds: Thank you for your kind thoughts about the hospice system in Connecticut.

Your comments regarding the euphemisms that are used to cloak the process of dying have some validity. However, hospice is not concerned about dying because patients whose lives will be measured in days, weeks or months need to be supported in their living. Hospice is concerned with improving a dying person's quality of life, and that of the family, for as long as life lasts.

Hospice provides care by a medically-directed, nurse-coordinated, interdisciplinary team, not a "multi" disciplinary team. The team is led by doctors, who play an integral role in the continuity of the patient's plan of care, whether at home or in the hospital. A physician, in not abandoning a patient during the last part of life, adheres to what Dr. Robert Massey says in his essay, *When The Time For Heroics Has Passed:* "First of all, the patient must be given an opportunity to speak to his physician and to ask questions." We have never seen a hospice patient either at home or in the hospital, who has not asked, "Where is my doctor?" and/or "I want to speak to my doctor." The appropriate title of ***Physician Assisted Living*** was coined to give the deserved prominence to our doctors for leading the interdisciplinary teams that allow Hospice to bring life to days, not days to life.

Is There a Place for Hospitalists in Health-care Reform?

Letter to the Editor: The need for more primary-care doctors has been expressed as early as 1932 with the report of the Committee on the Costs of Medical Care. It was followed by the Millis Commission Report (1966), and recently by the reports of the Association of American Medical Colleges' Task Force on the Generalist Physician (1992), the Josiah Macy Foundation (1993), the PEW Charitable Trust (1996), and the Institute of Medicine (1997).

However, organized medicine has distinguished itself neither by increasing the number of primary-care doctors or encouraging the development of primary care significantly; in fact some observers have noted that primary care is accorded second-class status in academic health care centers.[1]

This lack of support explains why primary-care doctors are not being trained in sufficient numbers to achieve the 50-50 balance between them and specialists that health-care analysts have consistently recommended. Thus, it should not be surprising that HMOs are employing nurse practitioners in greater numbers as surrogates.[3,4] Interestingly in Canada where there is more balance between the numbers of primary-care doctors and specialists, nonphysicians are not moving into primary care.[5]

However, the substitution of nurse-practitioners for primary-care doctors may soon be reversed by a new category of physicians—"hospitalist"—whose main function is to take care of primary-care doctors' hospitalized patients. In a sense, these new physicians "increase" the number of primary care doctors by making them more efficient and more available for outpatient care.[6,7] In this way they can fill the voids that encouraged HMOs to use nurse practitioners in place of generalists. Currently, primary-care doctors are scurrying to provide care to patients in their offices, nursing homes, hospitals (including the intensive care unit), and in their homes. Some of them lament that hospital practice takes up an inordinate amount of time and energy and diminishes their overall productivity. Add to this the difficulty of keeping up with new developments, the high expectations of patients, and the constant threat of malpractice and it becomes obvious why many have considerered limiting their hospital practices. In addition, an increasing number of patients are being discharged to nursing homes with serious illnesses requiring ongoing care which requires a notable amount of primary-care doctors' time, including frequent telephone calls to nurses and patients' families.

By using hospitalists primary-care doctors will be able to devote more time to outpatient care—which is what most of them do best. We may even see the return of the housecall, which has all but disappeared but is still greatly desired by patients.[8]

There are two arguments critics usually raise against the use of hospitalists. First, they say that the doctor-patient relationship will suffer. Theoretically this is true, but in reality it can be minimized if lines of communication are kept open between hospitalists and their generalist counterparts. Secondly, some generalists worry that their hospital skills will diminish. This is a legitimate concern, but have they not diminished already because of inability to keep up with the complexity of hospital care? Is not the growing complexity of hospital practice merely the normal evolution of medical science? And are not hospitalists a step forward in that evolution? It seems to be in the best interests of hospital patients to delegate their care to those who are especially trained and motivated to coordinate their care, treat them with the least waste of resources, and get them home as soon as possible. This is of particular importance in a health-care system like ours that is committed to cost-effectiveness.

On balance, it seems that hospitalists are one of the true innovations to come out of health-care reform. They have great potential to improve the provision of health care. Patients will accept them if they understand that they will be referred back to the care of their personal physicians, and that their personal physicians will be involved in all critical decisions. Hospitalists themselves will have the biggest challenge to making the hospitalist-generalist team succeed, for it is they who will have to take up in midstream where primary-care doctors leave off. For example, they will have to provide not only the medical expertise needed for inpatient care, but they will have to radiate the friendly warmth and reassurance usually imparted by the patient's personal physician.

The hospitalist concept is a good idea and primary-care doctors who decide to work with hospital doctors will have to find their own individual comfort levels. But to the degree that they do use them, they will have more time to devote to what they do best and in enlarging their outpatient repertory of skills. Furthermore, the use of hospitalists has the potential to give generalists more family and personal time, to lessen what Sir William Osler aptly described as the "... incessant demands of the general practitioner."

Physicians are often criticized for complaining abut health-care reform but not coming up with any solutions. The use of hospitalists definitely is one solution.

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Edward J. Volpintesta, M.D.
Bethel

From the Executive Director's Office

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1998 Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway, Meriden. The meeting will commence at 12:30 P.M. on Wednesday, 13 May and will continue until all business has been concluded. Governor Rowland and Mrs. Barbara Kennelly have been invited to speak at the meeting.

Stanley J. Keating, M.D., President
Howard J. Wetstone, M.D., Speaker of the House
John P. Bigos, M.D., Secretary

11:30 A.M.	Luncheon and Registration of Delegates
12:30 P.M.	Call to Order
	Adjournment at Conclusion of Business
	Reception for the Incoming President

MEMBERS OF THE HOUSE OF DELEGATES

The President of the Society
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All past-presidents of the Society and alternate delegates are ex-officio members of the House of Delegates without the privilege of voting. (Complete lists of delegates were not available from the county associations in time for publication in this Handbook.)

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member, or Postgraduate physician Member of The Society in compliance with the following provisions:

a. All resolutions, reports, and similar items of business submitted in writing and received at the office of the Executive Director not later than 30 days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.

b. Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than 35 days prior to the date of the House of Delegates shall be allowed five days after the close of such meetings in which to submit resolutions, reports, and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than 15 days prior to the date of the meeting.

c. Reports, recommendations, resolutions, or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.

d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred as once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.

IN MEMORIAM

CASSELL, ROBERT T., Faculté de Médecine de la Université de Genève, Switzerland, 1954. Dr. Cassell, an internist and rheumatologist, practiced in Bridgeport until his retirement in 1993. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Cassell died 1 February 1998 at the age of 77.

CONTE, MARIO G., Facolta di Medicina e Chiurgia della Universita di Napoli, Italy, 1935. Dr. Conte was a practicing physician and surgeon in New Haven for 60 years and a member of the surgical staff at The Hospital of St. Raphael. He was a member of the New Haven County Medical Association where he served as a delegate to the Connecticut State Medical Society from 1973 to 1979, the Connecticut State Medical Society, and the American Medical Association. Dr. Conte died 6 February 1998 at the age of 87.

DICKINSON, WILLIAM W., University of Pennsylvania School of Medicine, 1942. Dr. Dickinson was the medical director of the Hartford Small Plant Medical Service for 35 years retiring in 1988. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society where he served on the Committee on Occupational Health for 10 years, and the American Medical Association. Dr. Dickinson died 15 February 1998 at the age of 82.

DORIAN, EDWARD, University of Maryland School of Medicine, 1937. Dr. Dorian began his private medical practice in 1939 in New Britain. Following his retirement from practice in 1975, he was employed at Pratt & Whitney in industrial medicine and also worked for the Connecticut Department of Health. For many years, he served as physician to the New Britain Police Department. In addition to the New Britain Medical Society, Dr. Dorian was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Dorian died 7 January 1998 at the age of 90.

FIERBERG, A. ARTHUR, University of Pittsburgh School of Medicine, 1949. In 1957, Dr. Fierberg opened a private allergy practice in Hartford retiring from there in 1993. He was active in local and national allergy societies and served as a past president of the Connecticut Allergy Society. Dr. Fierberg was a member of the Hartford County Medical Association, the Connecticut State Medical Society where he served on the Liaison Committee with the Department of Income Maintenance from 1982 to 1985, and the American Medical Association. Dr. Fierberg died 29 December 1997 at the age of 76.

FLEMISTER, ADOLPH S., Howard University College of Medicine, 1954. Dr. Flemister practiced medicine in the greater Bridgeport area for 38 years. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Flemister died 10 December 1997 at the age of 73.

GELBERG, ELIZABETH, New York Medical College, 1985. Dr. Gelberg specialized in obstetrics and gynecology and was associated with Brookside Obstetric and Gynecology Associates in Greenwich. She was a member of the Fairfield County Medical Association, the Connecticut State Medical Society where she served on the Maternal Morbidity and Mortality Committee, and the American Medical Association. Dr. Gelberg died 21 December 1997 at the age of 39.

HARRIS, H. PATTERSON JR., Duke University School of Medicine, 1936. Dr. Harris obtained a masters degree in public health from Yale in 1965 and was a retired medical examiner. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Harris died 5 January 1998 at the age of 87.

HERBSTRITT, JOSEPH G., State University of New York at Buffalo School of Medicine, 1963. Dr. Herbstritt, a plastic surgeon, had his first practice with the Long Island Plastic Surgical Group in Mineola, New York. He began his private practice in Brookfield in 1981, retiring in 1995. Dr. Herbstritt served a term as chief of surgery at New Milford Hospital. He was cofounder of the Northeast Division of Heal the Children in New Milford. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Herbstritt died 29 December 1997 at the age of 60.

MAGRAM, HERBERT M., Columbia University College of Physicians and Surgeons, 1952. Dr. Magram, an obstetrician and gynecologist, practiced medicine in Middletown for 30 years. He served as chief of gynecology at the Middlesex Memorial Hospital from 1961 to 1972 and as chairman of the Department of Obstetrics and Gynecology from 1974 to 1979. He was assistant clinical professor in obstetrics and gynecology at the Yale University School of Medicine. In 1980, Dr. Magram accepted a full-ime appointment as associate professor of obstetrics and gynecology at the University of Miami School of Medicine, returning to Connecticut in 1984 as chief of obstetrics and gynecology at Mt. Sinai Hospital and associate professor of obstetrics and gynecology at the University of Connecticut School of Medicine. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Magram died 16 February 1998 at the age of 72.

RAFFAELE, FRANK J., University of Western Ontario Faculty of Medicine, Ontario, Canada, 1930. Dr. Raffaele was on the staff at St. Joseph Medical Center and Stamford Hospital in Stamford and Wickersham Hospital in New York City as an ear, nose, and throat specialist. He also maintained private practices in New York, Stamford, and Old Greenwich. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Raffaele died 18 December 1997 at the age of 91.

IN MEMORIAM *continued*

ROGERS, MARTIN C., John Hopkins University School of Medicine, 1932. Dr. Rogers practiced family medicine in Manhattan prior to his relocation to Stamford in 1965. He was on the staff at St. Joseph Medical Center and had a private practice in Stamford, retiring in 1987. He was a member of the Fairfield County Medical, the Connecticut State Medical Society, and the American Medical Association. Dr. Rogers died 9 January 1998 at the age of 89.

WILCOX, LLOYD M. SR., Tufts University School of Medicine, 1933. Dr. Wilcox began his medical career as a general practitioner in Terryville and was the company physician for the former Eagle Lock Company of Terryville. He then practiced ophthalmology in Terryville and in Bristol, retiring in 1988. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Wilcox died 5 February 1998 at the age of 91.

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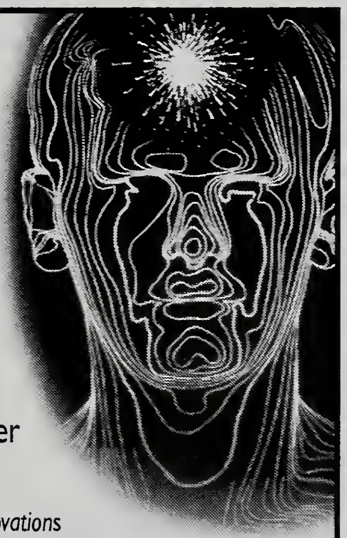

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***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

Announcements on the Physician Placement Service page under Classified Advertising are charged at the regular Classified Advertising rate.

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Papers prepared on a word processor should be submitted on a diskette along with the hard copy. Please send them to:

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Fitzroy A urland 199 **Significance of Coagulase-negative Staphylococci in Urinary Tract Infections in a Developing Country**

senberg 205 **Systemic Cat Scratch Disease: A Brief Case Report and Review of the Literature**

M kmiller, l Cohen 209 **Intrinsic Hemangiomas of the Peripheral Nerves Report of a Case and Review of the Literature**

Elizabe Horwitz, Collee Roberto 215 **Monitoring Clinical Quality in Medicaid Managed Care**

David I. r, Bruce Paturzo 221 **Ongoing Physician Guidance to Achieve Periodic Mammography of Women at an Urban Health Center**

Epitomes of Progress
226 **Important Advances in Clinical Medicine—Allergy and Immunology**

commentary:

Joseph F. Bentivegna 235 **The Need for Single-payer Catastrophic Health Insurance**

departments:

Fifty Years Ago
239 **The Hartford Hospital Medical Center**

The President's Page
Stanley J. Keating, Jr. 241 **Engaged in the Dialogue**

Reflections on Medicine
Robert U. Massey 243 **Tragic Fall or Angle of Repose?**

Medical News Capsules
Timothy B. Norbeck 245 **This Month's Reading in Review**

Letters to the Editor
nd Robert M. Greenstein 246 **Cancer Gene Testing?**
Charles W. Needham 246 **So What About Character?**

From the Executive Director's Office
CSMS 247 **Call**

general:

249 **In Memoriam**
251 **Book Reviews**
254 **CSMS Physician Placement Service**

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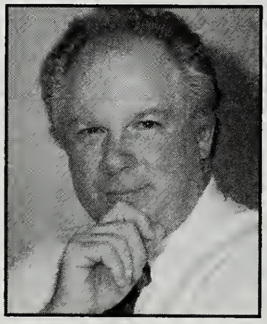

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A Rare Manifestation of Parathyroid Carcinoma Presenting as a Cystic Neck Mass

PAUL PIRUNDINI, M.D., ALAE ZARIF, M.D., AND JOSEPH G. WIHBEY, M.D.

ABSTRACT—Parathyroid carcinoma is a rare endocrine neoplasm. An unusual case is reported where a patient presented with a cystic neck mass and hypercalcemia. A review of the Connecticut Tumor Registry data revealed that four cases were encountered statewide over years 1988 to 1993. A brief overview of the current literature follows.

Case Report

THE patient is a 48-year-old white female who presented with an eight-month history of a palpable mass in the left side of her neck. The patient has a long history of bipolar disorder, manic-depression, and had noted a worsening of symptoms for several months. The patient's symptoms included a 15-pound weight loss and insomnia, noting that she generally had slept one to two hours each night over the last month. The patient's medications included Mellaril® (thioridazine), Desyrel®, (razodone) and Depakote® (divalproex sodium). The patient denied symptoms of upper airway compression or changes in her voice. There was no history of nephrolithiasis, bone disease, or peptic ulcer disease.

On physical examination, the patient weighed 70 kg and was in no distress. Vital signs were stable with a blood pressure of 138/72 mmHg and pulse of 74. Of note, a palpable 3 x 4 cm mass was felt in the left anterior neck suggesting a thyroid mass. It was firm and it was not adherent to the overlying skin.

A thyroid scan was obtained (Fig. 1) and this demonstrated a left-sided solitary cold nodule thought to be consistent with a thyroid mass. A needle aspiration was performed and yielded 5 mL of clear greenish fluid. The mass could no longer be felt after aspiration. The patient returned one month later with a recurrence of the mass. A second needle aspiration was performed which yielded 10 mL of serous fluid. Again, after this the mass was no longer palpable. Cytologic evaluation of the fluid was negative for malignant cells. The patient returned a third time, again approximately one month later, with a recurrence of the mass and aspiration was again performed with a 5 mL return of serosanguinous fluid. Laboratory values were obtained including normal thyroid function tests, white blood cell count of 6,400, hemoglobin 11.8g, platelet count of 365,000, and a normal coagulation profile and urinalysis. The patient's electrolytes were remarkable for an elevated calcium of 11.8 mg/dL and phosphorus of 2.3 mg/dL. Additionally, the patient's parathyroid hormone level was markedly elevated at 177 pg/mL (normal 10-65 pg/mL).

The patient was taken to the operating room where a neck exploration was performed for excision of the neck mass thought possibly to be of parathyroid origin. At the time of operation, a cystic mass was identified posterior to the left thyroid lobe. This mass was dissected away from the surrounding tissue using sharp and blunt dissection. No lymphadenopathy was noted at the time of initial excision. The mass was sent to the pathology laboratory for evaluation. The mass was ovoid, measuring 4.3 x 2.5 x 2.5 cm. The external surface was smooth and was pinkish tan in color. The cut surface revealed the specimen to consist largely of a central cyst space filled with chocolate brown fluid. The adjacent parenchyma was

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noted to be pinkish purple with focal areas of pale gray tissue. Histologic examination was consistent with parathyroid carcinoma. Present histologically was a thick fibrous capsule infiltrated by nests of tumor cells. The tumor also demonstrated a trabecular growth pattern. There was no evidence of vascular invasion. Confirmation of these findings was obtained from Dr. Paul Goudin at Memorial Sloan-Kettering Cancer Center in New York.

The patient was taken back to the operating room on 19 December 1995 for a more extensive resection. At that time, a left thyroid lobectomy and isthmusectomy was performed which included excision of the remaining parathyroid gland on the left and regional lymph node dissection. This tissue was negative for malignancy. The parathyroid gland was noted to be relatively small.

Twelve- month follow-up revealed that the patient was doing well. There was no significant improvement in her psychiatric symptoms, however, she did demonstrate improved sleep habits with an average of six hours of sleep nightly. The patient reported an 11 pound weight increase. Additionally, the patient's serum calcium and PTH normalized.

Discussion

Parathyroid carcinoma is a rare endocrine neoplasm that occurs in less than 1% of patients with primary hyperparathyroidism.[1] The actual incidence is difficult to determine because inadequate histologic criteria may have lead to overreporting.[2] Histologic criteria for this disease entity remain controversial; some feel that the diagnosis is clear only in the presence of local invasion or distant metastasis. Histologic features that can be associated with malignancy include a fibrous trabecular pattern, mitotic figures, a thick capsule, a uniform cell pattern, and invasion into blood vessels and the capsule.[3,4] Although all are not invariably found, several are usually present.[3]

A slight female preponderance is noted in parathyroid carcinomas in the United States. The SEER data included 64 cases of parathyroid cancer between the years 1973 and 1987. Of this group, 29 were male and 35 were female. A review of the Connecticut Tumor Registry 1988 to1993 reveals that of the four known cases in Connecticut, all were male. Large series of parathyroid carcinoma include Holmes[5] who reviewed 50 cases in 1969 and Schank[5] who reviewed 70 cases in 1973. We reviewed all of the findings

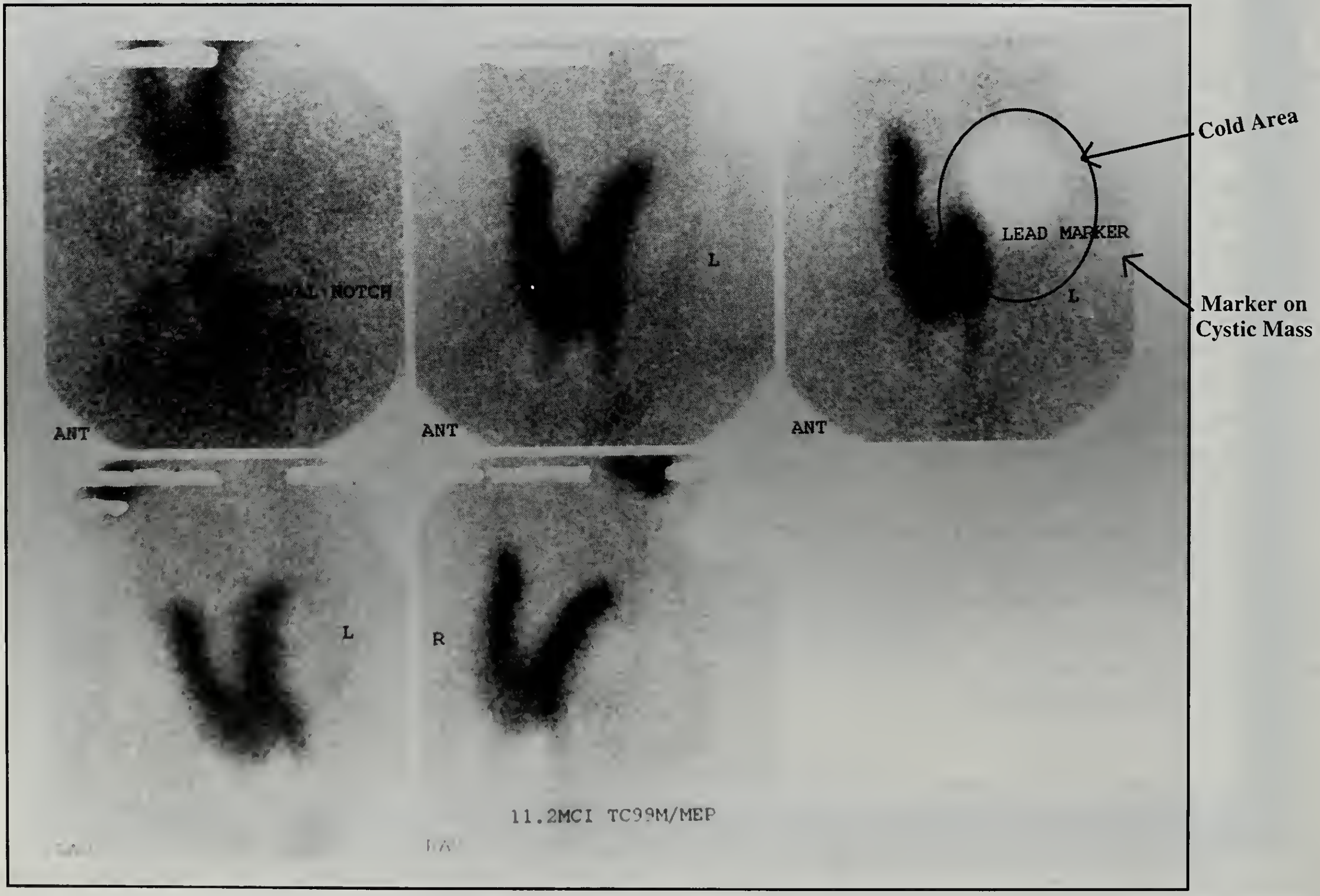

Figure 1.—Thyroid scan showing left upper lobe cold nodule—lead marker over cystic mass.

in these studies and in no case did a parathyroid carcinoma present as a cystic mass. Therefore we feel the presentation of this case is unique.

Patients with parathyroid carcinoma tend to have nonspecific symptoms. They may include depression, weight loss, fatigue, weakness, nephrolithiasis, bone disease, constipation, peptic ulcer disease, and pancreatitis.[4,5]

Three clinical features described in the literature are more consistent with carcinoma as opposed to benign disease. These include, 1) palpable neck mass, 2) evidence of bone disease radiographically, and 3) high serum calcium.[3-5,7]

In general, patients with malignant disease tend to be younger as well as more symptomatic.[3] Serum calcium levels appear to be higher in patients with malignant disease.[8] Silverberg reports an average calcium level of 11.7 mg/dL[14] in a study of primary hyperparathyroidism. This is compared with a mean calcium value of 15.9 mg/dL reported by Holmes et al in patients with parathyroid carcinoma.[5] Although it should be noted that he also presented four patients in that study with normal calcium levels and who were otherwise asymptomatic. The case presented here showed a calcium level that was lower than that expected for malignant disease.

Parathyroid hormone levels tend to be higher in patients with parathyroid carcinoma.[8] It is noted by Aldinger, that nonfunctioning parathyroid carcinoma may be more aggressive.[9]

In treatment of parathyroid carcinoma, the initial approach is generally wide surgical excision. These tumors tend to invade locally and metastasize to local lymph nodes.[8] The capsule should be kept intact during the dissection and include a margin of normal tissue. Some authors suggest an ipsilateral thyroid lobectomy and isthmusectomy.[10] If the recurrent laryngeal nerve is adherent to the tumor, it may need to be sacrificed.[10] In the past, prophylactic radical neck dissections have been advocated; this is no longer supported in the literature, as morbidity with that procedure is greatly increased and no survival benefit has been observed.[10] However, clearly the excision should include local lymph nodes with the specimen. According to Flye and Brennan, reviewing the NCI statistics in 1981, there is a 32% incidence of cervical lymph node metastasis.[10,11] The initial surgical excision of a parathyroid carcinoma offers the best hope for cure.[1] Most studies show that cure after recurrence is uncommon.[12]

The response of this tumor to chemotherapeutic agents has generally been poor, although a few reports of success in recurrent disease have been published. Chahinian reported a remission in a patient with a nonfunctioning recurrent parathyroid carcinoma treated with adriamycin, methotrexate, cyclophosphamide, and Methyl CeeNu (lomustine). Calandra and colleagues report a partial response followed by relapse in a patient with recurrent disease with the use of dacarbazine.[14]

By and large, radiation therapy has not been successful in treating these tumors.

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Significance of Coagulase-negative Staphylococci in Urinary Tract Infections in a Developing Country

FITZROY A. ORRETT, M.D. AND SIMONE M. SHURLAND M.Sc.

ABSTRACT—The biotyping of 154 (3.8%) coagulase-negative staphylococci from 4,051 urinary specimens in males and females was performed. Their significance and antimicrobial susceptibility patterns were also evaluated. *S. saprophyticus* and *S. epidermidis* accounted for approximately 90% of isolates from females, while in males only 68.7% of isolates were *S. epidermidis, S. hominis, S. xylosus, S. simulans,* and *S. hyicus.* The mean age for females with infections due to *S. saprophyticus* was 23 years while for males with infections due to *S. epidermidis* it was 77 years. The mean age for infections due to other staphylococci was higher in males than in females. There was little variation in the antimicrobial susceptibility pattern in the various species.

The results suggest that apart from *S. saprophyticus* and *S. epidermidis, six* other species of coagulase-negative staphylococci (*S. hominis, S. xylosus, S. simulans, S. hyicus, S. hemolyticus,* and *S. cohnii*) account for most urinary tract infections irrespective of gender.

Introduction

COAGULASE–NEGATIVE staphylococci (CNS) are often isolated from urine specimens, frequently in quantities considered clinically significant.[1,2] One of the major problems encountered by the laboratory is distinguishing clinically significant pathogenic strains of CNS from contaminant strains.[3] Micrococcus biotype III *(Staphylococcus saprophyticus)* became the first coagulase-negative staphylococcus with recognized clinical significance.[4-6] Recognition of the pathogenicity of this coagulase-negative staphylococcus, together with the increasing significance of the group of *Staphylococcus epidermidis* as nosocomial pathogens, has highlighted the need for fuller species identification of the coagulase-negative staphylococci. The present study was undertaken to characterize the features of bacteriuria due to CNS in Trinidad, W.I., by correlating species identification using the biotyping schema of Kloos and Schleifer[7] and the International Committee on Systematic Bacteriology:[8] recommendations with antimicrobial susceptibility and clinical features.

Materials and Methods

Between January and October 1995, 4,051 specimens of urine were received in the diagnostic laboratory of the Eric Williams Medical Sciences Complex (EWMSC) from centers within the Central Regional Health Authority (about a 50-mile radius), for analysis. Trinidad is the larger of a twin-island republic (Trinidad and Tobago) with a population of about 1.25 million and located about seven miles off the northern coast of Venezuela. Specimens were received from inpatients, emergency room and outpatient clinics, general practitioners, and the surrounding health centers. Samples came in wide-mouth screw-on top sterile containers in eight-quart Coleman coolers via couriers and arrived in the laboratory about one to two hours from the centers and placed in the refrigerator (4°C).

All samples are processed within one hour after arriving at the laboratory. However, the time of collection of a specimen was not always stated on samples from health centers, but if in this event there was no reason to suspect delay in transit to the laboratory, strains were retained

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Table 1.—Coagulase-negative Staphylococci Isolated from Urinary Tract Infections

Species	Male N = 32 No.	Male N = 32 %	Female N = 120 No.	Female N = 120 %	Total N = 151 No.	Total N = 151 %
S. saprophyticus	10	31.3	88	74.6	98	65.3
S. epidermidis	8	25.0	19	15.8	27	17.4
S. hominis	4	12.5	3	1.7	7	4.0
S. xylosus	4	12.5	2	1.7	6	4.0
S. simulans	4	12.5	2	1.7	6	4.0
S. hyicus	2	6.2	2	—	4	1.3
S. hemolyticus	—	—	4	3.4	4	2.7
S. cohnii	—	—	2	1.7	2	1.3

from profuse pure growths which indicated the possibility of infection. A standard calibrated loop delivering 0.001 mL of uncentrifuged urine was used to inoculate sheep blood agar (SBAP) and cysteine lactose electrolyte deficient (CLED) media. These plates were incubated aerobically at 37°C for 18–24 hours. The colony count was expressed in colony-forming units (CFU) per millimeter of urine. Specimens of urine containing $>10^5$ organisms per mL of a single species were considered as having significant bacteriuria. Three or four colonies from each positive culture were processed to ensure that only one species of CNS was present. Wet preparations were made from centrifuged samples, and casts, leukocytes, and erythrocytes per high power field were looked for. A rapid dipstick (Combur 10 Test, Boehringer Manheim, Diagnostics and Biochemicals, East Sussex, United Kingdom) was also used to detect pyuria via leukocyte esterase activity.[9] Staphylococci were identified initially by using the criteria of Kloos and Schleifer.[7] All species that were other than *S. epidermidis* and *S. saprophyticus* were re-evaluated by using the Staph-Ident System (bioMenieux Vitex, Inc., Hazelwood, Montana, United States). Antibiotic susceptibility tests were performed by the Kirby-Bauer disc diffusion method.[10] Antibiotic discs containing the following concentrations were used: ampicillin (10μg), cephalothin (30μg), gentamicin (10μg), trimethoprim-sulfamethoxazole (30mg), tetracycline (30μg), nitrofurantoin (300μg), amoxicillin-clavulanic acid (20/10mg) and erythromycin (15μg). The diameter of inhibition of growth was measured and susceptibility determined by predetermined breakpoints. Beta-lactamase production was detected using Oxoid Indentification Rods (Unipath Ltd., Hampshire, England). The tip of each rod was impregnated with a solution of nitrocephin, a chromogenic cephalosporin that produces a rapid color change from yellow to red when the β-lactam ring is hydrolyzed by a β-lactamase. A positive reaction was shown by the development of a pink/red color visible within five minutes. A negative reaction was indicated by no color change within 15 minutes and the absence of β-lactamase. *Staphylococcus aureus* NCTC 1156 strain was used as a positive control while unused sticks served as negative controls.

Table 2.—Ages of Patients with Urinary Tract Infections Due to Coagulase-negative Staphylococci

Species	Male Mean (years)	Male Range (years)	Female Mean (years)	Female Range (years)
S. saprophyticus	34.7	4–76	23.2	3–57
S. epidermidis	77.0	70–89	52.6	18–87
S. hominis	65.0	41–74	44.6	39–47
S. xylosus	54.0	40–68	40.0	30–50
S. simulans	32.5	25–40	34.0	29–43
S. hyicus	75.0	63–87	—	—
S. hemolyticus	—	—	33.0	19–47
S. cohnii	—	—	27.0	20-36

Table 3.—Comparison of Reported Rates of Isolation from Infected Urine of Coagulase Negative Staphylococci

Species	**Present Study**	**Leighton**[12]	**Gill**[15]	**Gemmel**[18]	**Marsik**[11]	**John**[6]	**Nord**[19]
S. saprophyticus	64.0*	51.0	11.0	13.0	95.0	5.0	44.0
S. epidermidis	17.5	25.0	63.0	30.0	19.0	53.0	23.0
S. hominis	4.5	2.0	—	1.0	18.0	12.0	7.0
S. xylosus	3.9	—	—	4.0	—	—	—
S. simulans	3.9	2.0	6	—	—	5.0	2
S. hyicus	2.6	—	—	—	—	—	—
S. hemolyticus	2.6	11.0	9.0	4.0	19.0	10.0	14.0
S. cohnii	1.3	—	—	—	17.0	—	—

*percentage of isolates

Results

Of the 4,051 specimens of urine received in the laboratory, only 154 (3.8%) yielded a bacteriologically significant growth of Gram-positive, coagulase-negative, catalase-positive cocci. Table I shows the number of strains isolated for each species of staphylococcus subdivided according to the gender of the patients. *S. epidermidis* and *S. saprophyticus* accounted for ~ 90% of the infections in females. In males *S. saprophyticus* and *S. epidermidis,* accounted for 31% and 25% respectively, with *S. hominis*, *S. xylosus*, and *S. simulans* accounting for 13% each. Only two strains (1.3%) of *S. hyicus* and *S. cohnii* were isolated.

Table 2 lists the ages of the patients with staphylococcal urinary infections. Females showed a mean age of 23 years for *S. saprophyticus* and 18 to 50 years for the other organisms, whereas males showed a mean age of 33 to 77 years for *S. epidermidis*, *S. hominis*, and *S. hyicus*, and 35 years for *S. saprophyticus*.

Table 3 compares the results of our study with other reports of CNS isolates, while Table 4 summarizes the antimicrobial susceptibility patterns of the isolates. As shown, 50 to 85% of *S. epidermidis* and *S. hemolyticus* isolates were resistant to ampicillin. Isolates of both these species, as well as the others, were tested for and were positive in varying degrees for β-lactamase production using a chromogenic method. All isolates were uniformly susceptible to norfloxacin and gentamicin and the two strains each of *S. cohnii* and *S. hyicus* were susceptible to the nine antimicrobials tested. *S. saprophyticus* strains were sensitive to more than 80% of six antimicrobials.

Table 4.—Sensitivity Pattern of Coagulase-Negative Staphylococci Isolates from Urinary Infections
Proportions (%) of Strains Sensitive to Various Antimicrobials

Antimicrobials	***S. saprophyticus*** **N = 98**	***S. epidemidis*** **N = 27**	***S. hominis*** **N = 7**	***S. simulans*** **N = 6**	***S. xylosus*** **N = 6**	***S. hemolyticus*** **N = 4**	***S. hylcus*** **N = 4**	***S. cohnii*** **N = 2**
Ampicillin	81	15	83	0	0	50	100	100
Cephalothin	81	69	67	67	33	100	100	100
Co-amoxiclav	100	62	100	67	100	100	100	100
Gentamicin	100	100	100	100	100	100	100	100
Nitrofurantoin	63	38	67	0	0	0	100	100
Tetracycline	69	83	83	0	33	0	100	100
Co-trimoxazole	94	83	83	67	100	50	100	100
Erythromycin	75	54	100	67	33	50	100	100
Norfloxacin	100	100	100	100	100	100	100	100

Statistical analysis for differences in resistance rates: *S. saprophyticu vs S. epidemidis.* $P < 0.001$ ($\chi^2 = 190.02$)

Susceptibility was between 60% to 65% for nitrofurantoin, tetracycline,and erythromycin. A similar pattern was seen for *S. epidermidis*, except for tetracycline. *S. xylosus* demonstrated the least sucsceptibility to cephalothin, tetracycline, and erythromycin (33%).

Discussion

In our laboratory *S. saprophyticus* was the most frequent coagulase-negative staphylococcal species isolated from the urine specimens followed by *S. epidermidis*. These findings agree with work done elsewhere.[11-14] All other CNS comprised approximately 18% of the isolates. This distribution is comparable to that reported by Johns,[6] Leighton,[12] Gill,[15] and their associates using the same biotyping system (Table 3). Gill et al[15] and John et al[16] also using the same biotyping system did not find *S. saprophyticus* to be a major isolate. The latter examined urine isolates (>10^7 organisms/mL) primarily from male patients in a Veterans Administration Hospital and obtained results similar to those for the male patients in this study (Table 1). The Gill et al[15] 63% predominance of *S. epidermidis* is similar to that of John et al[6] but no indication was given by Gill et al[15] as to the distribution of the gender of the patients. Also although both groups of researchers' results are in agreement the discrepancy between their and our results may be that their study population consisted primarily of male inpatients and a small proportion of female outpatients. *S. saprophyticus* is unique among staphylococci in that it is primarily restricted to young female outpatients. The prevalence of the other CNS isolates in females apart from *S. epidermidis* remained essentially constant (1.6%), except for *S. hemolyticus* which was 3.3%. The corresponding values for males was also relatively constant for *S. hominis, S. xylosus*, and *S. simulans* at 12.5%. It would appear that the pathogenic potential of these organisms is affected by the gender of the patient and that *S. epidermidis is* the second most commonly involved coagulase-negative staphylococcus in urinary tract infections.

The age distribution emphasizes a difference between the two sexes (Table 2). Females showed a mean age of 23 years for *S. saprophylicus* infections and males a mean age of 77 years for *S. epidermidis* infections. These results are similar to previously reported findings[13-14] which showed a mean age of 22 to 25 years for females with urinary tract infections (UTIs) due to *S. saprophyticus* and 60 to 72 years for male and female patients with UTIs due to other species of staphylococci. Significant differences were also recognized in the antimicrobial susceptibility patterns of the isolates. *S. epidermidis* strains were more resistant than *S. saprophyticus* strains and the other CNS strains to ampicillin (85% *vs* 19% to 50%), nitrofurantoin (62% *vs* 33% to 37%), cephalothin (37% *vs* 19%), and erythromycin (45% *vs* 25%) The differences were statistically significant ($P<0.001;\chi^2=190.02$). Staphylococci with minimum inhibitory concentrations (MIC) of greater than 0.05μg/mL are generally assumed to be β-lactamase producers.[16] All strains were 100% susceptible to gentamicin and norfloxacin. Gentamicin can only he given parenterally and should therefore be reserved for hospitalized patients. This means that norfloxacin, an oral antibiotic, should be the first choice for such infections, and co-amoxiclav as a possible alternative.

Our results show that apart from *S. saprophyticus* and *S. epidermidis,* there are six other species of coagulase-negative staphylococci (*S. hominis, S. xylosus, S. simulans, S. hyicus, S. hemolyticus,* and *S. cohnii)* that were also involved in UTIs in both males and females. These organisms, however, appear to have low pathogenicity and may require an elderly or immunocompromised host in order to establish an infection. The isolation of any of those six organisms from a properly-collected urine specimen should be suggestive of a UTI. Since there is minimal variation in the antimicrobial susceptibility of the various CNS species, and no apparent variation in the symptoms of UTIs caused by these organisms, routine speciation may be unwarranted. However, some circumstances where complete identification of the CNS may be useful include severely compromised patients, cardiac surgery patients, septicemic patients, and for epidemiologic investigations.[16] The results of our study suggest that speciation of CNS may also be useful in the assessment of UTI and the significance of the finding should be made clear to the clinician. By thus restricting speciation of CNS to special situation, the resources of the laboratory may best be concentrated in areas where resources will provide the most benefit, rather than becoming diluted.

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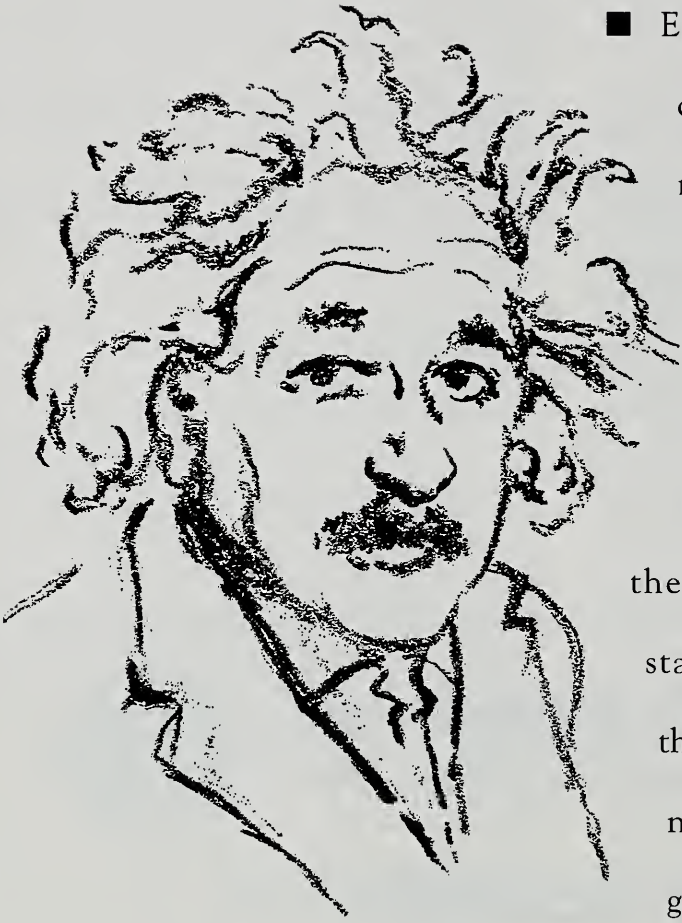

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Systemic Cat Scratch Disease: A Brief Case Report and Review of the Literature

RALPH ROSENBERG, M.D.

CAT scratch disease was recognized in the 1930s, and was first reported in the 1950s.[1,2] It is caused by *Bartonella henselae* (formerly *Rochalimaeo henselae*) a slow-growing, fastidious, gram-negative bacillus. Cat scratch disease is usually a benign, self-limited illness. Following a patient's contact with, or a scratch by a cat, a papule develops at the site of inoculation followed by regional lymphadenopathy.[3] The diagnosis of cat scratch disease traditionally required the presence of three of four criteria: contact with a cat and the presence of a scratch or primary lesion, a positive skin test, negative studies for other causes of lymphadenopathy, and characteristic histopathological findings.[4] This is now complemented by a serological test (indirect fluorescent antibody).[5] We describe a patient with diffuse systemic symptoms, corresponding serology, pathology, imaging studies, and treatment.

Case Report

A previously well 38-year-old white female presented on 24 February 1997 with two weeks of headache, abdominal pain, temperature to 38°C, fatigue, and a right axillary mass.

The patient had smoked one package of cigarettes daily. She did not drink alcohol. Prior history was significant only for herpes vaginalis and liposuction. The patient owned three dogs and two cats. She remembered being scratched on her chest by her cat a few weeks earlier.

Physical examination revealed a right axillary mass, but was otherwise unremarkable. A complete white blood cell count and differential was normal. The erythrocyte sedimentation rate was 99 mm/hr. SGPT was 75 milliunits/mL (normal to 34), SGOT 59 milliunits/mL (normal to 30), and alkaline phosphatase 229 U/L (normal to 110). Heterophile test was positive. Epstein-Barr nuclear antigen IgG was positive at high titers, consistent with previous infection. Hepatitis A, B, and C serologies were negative, (hepatitis B antibody was positive.) An ultrasound of the abdomen revealed a 2.3 cm mass overlying the head of the pancreas. The chest film was negative. A computed tomographic scan (CT) of the head was negative. A CT scan of the chest (Fig. 1) revealed para-aortic and pretracheal lymph nodes, as well as the right axilla adenopathy. A CT scan of the abdomen (Fig. 2) revealed a conglomerate mass or adenopathy overlying the para-aortic and retroperitoneal region and obscuring the pancreas. The spleen was enlarged but homogeneous.

The patient was treated with ciprofloxacin 750 mg b.i.d.. After two weeks her fever persisted, the sedimentation rate was 124, and the right axillary mass was unchanged. Cat scratch titer (*Bartonella henselae*) was positive at 2,048 (positive >128). Both toxoplasma and HIV antibodies were negative.

The right axillary node was excised. It was filled with a purulent material and the pathological examination revealed extensive necrotizing granulomas. All cultures (including acid-fast bacilli and *Bartonella*) were negative.

After two weeks of ciprofloxacin the abnormal liver function tests were normal; however, fever persisted, and the sedimentation rate remained high at 124 mm/hr. The patient developed right ankle pain, but roentgenograms were negative. A gallium scan was positive at the lacrimal glands bilaterally. Angiotensin converting enzyme level was normal. The patient developed a new I/VI systolic ejection murmur heard best at the left lower sternal border, and radiating to the apex. Splinter hemorrhages developed

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RALPH ROSENBERG, M.D., practicing internist in Avon.

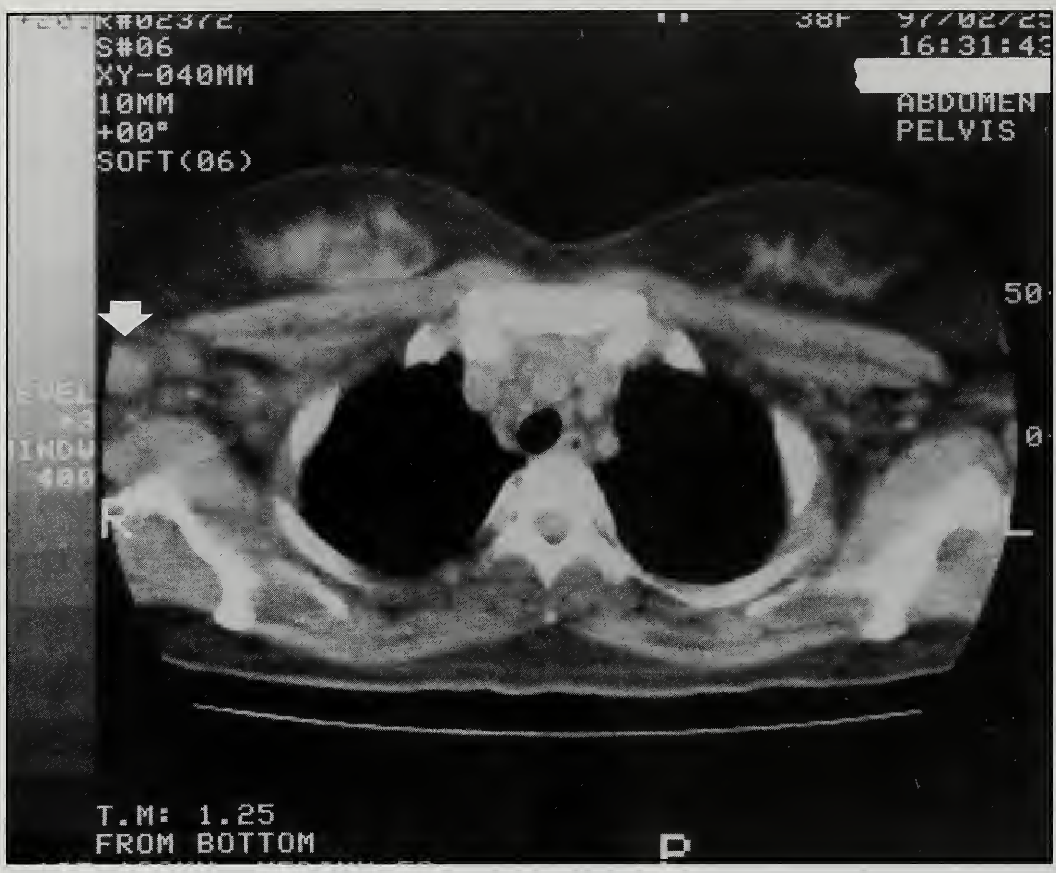

Figure 1.—Chest CT at the level of the midtrachea showing adenopathy. Right axilla adenopathy is also seen. (arrow)

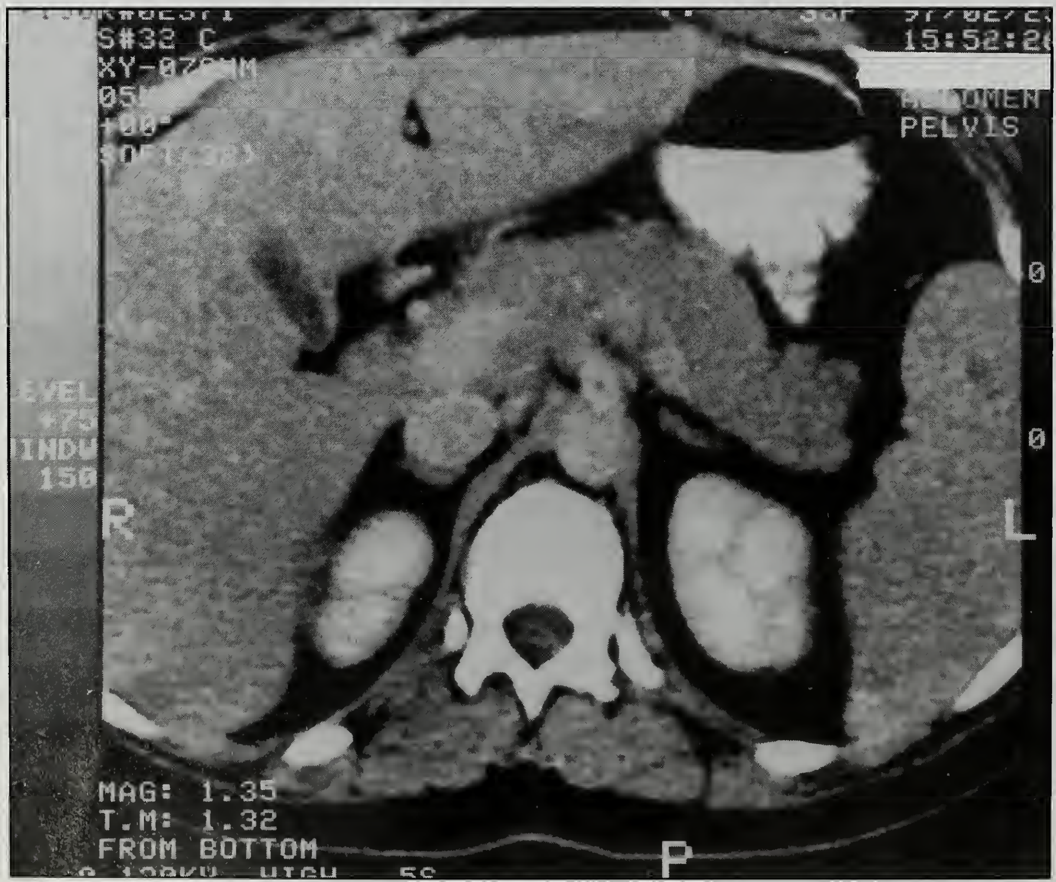

Figure 2.—Abdomen CT (magnification) at the level of the pancreas shows enhancement of an apparent mass in the head of the pancreas.

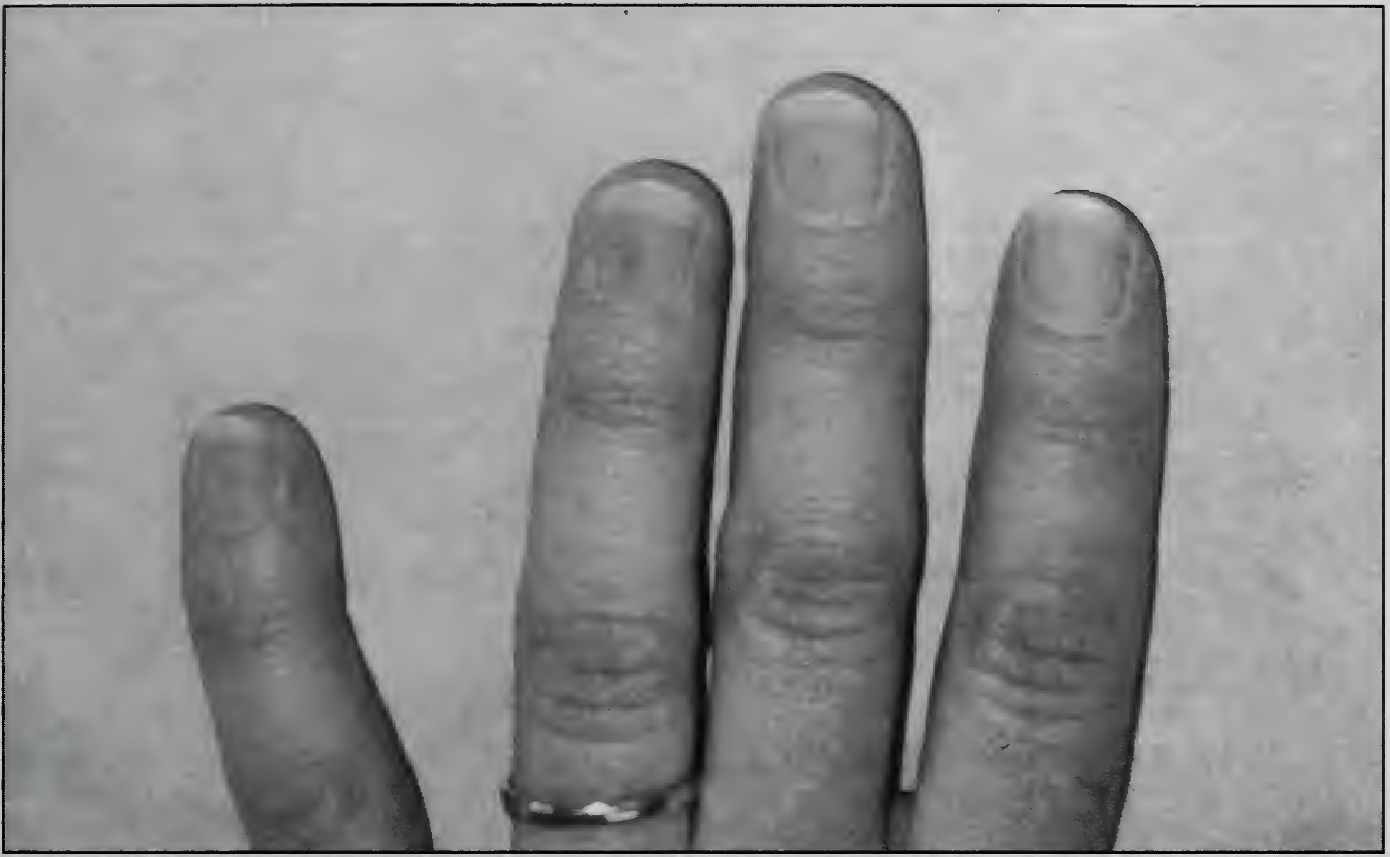

Figure 3.—Splinter hemorrhages at the finger nails.

at the finger nails (Fig. 3). An echocardiogram and blood cultures were negative. Doxycycline 100 mg b.i.d. was added, and the ciprofloxacin was continued.

After two weeks treatment with doxycycline the patient felt well and was afebrile. Her sedimentation rate was 69 mm/hr; after two additional weeks this had fallen to 26. A repeat CT scan of the abdomen and chest revealed resolution of all adenopathy, but the spleen was now heterogeneous.

Results

Although bacteria were never successfully cultured or stained, serology was strongly positive (performed at the Connecticut Department of Health Services). Zangwill has shown that an indirect fluorescent antibody test titer >1:64 had a sensitivity of 84%, and specificity of 96% for cat scratch disease.[5] The patient's titer was 1:2,048.

Other causes of adenopathy were excluded. A heterophile test was positive, however, Epstein-Barr nuclear antigen IgG titers were consistent with previous infection, and the patient did not have pharyngitis, cervical nodes, or show atypical lymphocytes. The histopathology supported a diagnosis of cat scratch disease, and there had been a history of cat scratch exposure.

Splinter hemorrhages indicated an embolic phenomenon and endocarditis. Raoult found that microimmune fluorescence assay greater than 1:1600 had a predictive value for *Bartonella endocarditis* of 0.884.[6]

Discussion

This patient fit the criteria for cat scratch disease, and the diagnosis had strong serologic support. The combination and degree of diffuse adenopathy, hepatic, splenic, neurologic, and embolic phenomena have not previously been described. Although ciprofloxacin has been reported to be effective therapy,[6] this patient did not improve until doxycycline was added. Gentamicin has been shown to be effective,[7] but cannot be given orally. First generation cephalosporins are not effective, whereas second and third generation cephalosporins, rifampin, tetracycline, chloramphenicol, trimethoprim-sulfamethoxazole, and macrolides may be effective.[8,9] Cat scratch endocarditis was first reported in 1993,[10] and may be associated with culture-negative endocarditis.[6] Further studies are required to determine the most effective therapy for cat scratch disease.

I am indebted to Mark D'Avignon, M.D., for his contribution of the CT scan images.

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Intrinsic Hemangiomas of the Peripheral Nerves
Report of a Case and Review of the Literature

M.T. ERGIN, M.D., WILLIAM H.DRUCKMILLER, M.D., AND PAUL COHEN, M.D.

ABSTRACT—A case of intrinsic hemangioma of the peripheral nerves and the diagnostic and therapeutic problems associated with these tumors is reviewed. Of the preoperative studies available, magnetic resonance imaging and to a lesser degreee computed axial tomography are the most helpful in diagnosis. Angiograms are not helpful. Specific laboratory studies to evaluate lymphoproliferative disorders are unnecessary if lymphadenopathy can be ruled out. Needle biopsies should be avoided as they may result in nerve injuries. During surgery the recognition of the tumor as a hemangioma is of prime importance in order to avoid damage to the nerve structures. More aggressive resections that might sacrifice the nerve should be postponed if an intraoperative diagnosis is not possible. This will provide for a complete histopathological evaluation rather than reliance upon frozen section interpretations.

HEMANGIOMAS are benign tumors of vascular origin. They are common and usually require no treatment, unless they occur in the very young, are conspicuous by their size and location, or arise in or near vital organs. However, hemangiomas arising from the vessels in the vicinity of the nervous system should be grouped separately and given special consideration. When they occur close to the peripheral nerves, differentiation from primary nerve tumors and the delineation of the relationship to the nerve fasicles is difficult to ascertain. Hemangiomas that arise and develop within the confines of the nerves comprise another subgroup that may be considered separately as intrinsic hemangiomas of the peripheral nerves. Although rarely encountered, in this subgroup the preservation of the peripheral nerve and its function is of foremost importance. In this report we present a case belonging to this subgroup to emphasize these points. Previously reported cases will also be reviewed.

In their early stages, intrinsic hemangiomas of the peripheral nerves usually present simply as a "lump." Usually there is no associated motor or sensory nerve deficit to direct attention to the nearby neural structures. As a result, accurate diagnosis is difficult to make solely from the presence of a swelling. As these tumors are typically discovered when they are small, magnetic resonance imaging (MRI) appears to be the most useful test in diagnosing the nature of the lesion accurately as well as determining its relationship to the neighboring peripheral nerves and vascular structures. The routine complete physical examination, coupled with basic laboratory studies and chest films are useful for general evaluation of the patient, but insufficient in determining the anatomical relationships of the tumor to other nearby structures. Needle biopsies, such as fine needle aspiration (FNA) or core tissue extraction, should be avoided. Open biopsies can be similarly dangerous. Unless the potential for nerve damage is recognized at surgery the nerve structures and their function may not be left intact. If the small tumor is differentiated from a lymph node, studies to evaluate lymphoproliferative diseases are unnecessary.

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A case meeting the criteria for this designation has prompted us to conduct a search in the world literature. We found only 10 reported cases to date. Therefore, it is no surprise that most current textbooks, monographs, and articles that deal with peripheral nerve tumors do not include this subgroup. A large body of reference was found in a paper by Losli[7] where he cited mainly older works, most notably by Stout, Ewing, and several others.[9] In the more modern literature a brief discussion of these tumors and references are found in Enzinger and Weiss, Soft Tissue Tumors.[1]

The earliest reference to these tumors is found in the German literature reported in 1913 by Sato.[2] Presenting two patients, he provided a detailed discussion of this entity. Both of Sato's patients were operated on in 1911 and, interestingly, only six months apart. The first of these tumors was located in the cervical plexus, and the other arose from the median nerve in the upper arm alongside the biceps muscle. The next paper, also published in the German literature, was a report of a case by Sommer in 1922.[3] This lesion originated from the confines of the posterior tibial nerve. In 1924 Stewart and Bettin in their review of angiomas, "Angioma of Nervous System,"[4] had recognized this tumor as a separate entity. They described a case of hemangiomatosis of the sciatic nerve that involved nearly the entire nerve with angiomatic tissue separating its tibial and fibular branches at the sciatic notch down to the heel along the sural nerve. The patient was a 10-year-old boy who had had lumps in his leg since age four. He had gradually developed severe pain in this extremity leading to inability to walk, flexion contracture at the knee, and marked muscle atrophy. After two unsuccesful attempts to excise these masses, an above knee amputation was eventually performed. Although the authors thought that the nerve was secondarily involved with the hemangioma, the operative and histopathological description is more consistent with primary intrinsic angiomas of the nerve itself, albeit in an extensive manner.

The next paper was published in 1925 by Schultze.[5] This report concerned a patient whose lesion arose from the posterior tibial nerve. In 1945 Purcell and Gurdjian reported a case which had been initially seen in 1932.[6] The tumor developed in the left sciatic nerve and was composed of multiple cyst-like dilatations that were growing between the fascicles, similar to the one described earlier by Stewart and Bettin. When first seen this patient was 21 months old and already had significant muscle atrophy of the lower limb accompanied by tenderness in the gluteal region. In the first operation they were able partially to excise parts of the tumor, those decompressing the nerve while simultaneously obtaining tissue for microscopic examination that revealed the benign nature of these cavernous hemangiomata. At a second operation they were able to dissect away much of the pathological tissue while preserving the function of the sciatic nerve, improving the existing muscle atrophy and restoring the normal gait. This conservative approach demonstrated for the first time that palliation was achievable without the sacrifice of the nerve for the treatment of these benign tumors. In 1952, Losli reviewing this subject used the term, "intrinsic hemangiomas of the peripheral nerves" for the first time while contributing two cases to the literature. One was in a middle-aged male whose tumor had developed within the left ulnar nerve at the elbow.[7] This self-neglected large tumor had already produced a functional deficit with resultant atrophy of the muscles enervated by ulnar nerve. Even though Losli must have been aware of the earlier report of Purcell and Gurdjian, because of concern for malignacy the nerve was sacrificed removing it with the mass. The other patient was a middle-aged female. Her tumor arose from the left fifth cervical nerve. Only a biopsy was done and the patient remained well thereafter, underscoring the wisdom of the conservative approach. The next reported case was in 1976 by Kojima and Marumo.[8] This patient was a 19-year-old female with carpal tunnel syndrome. Her lesion was located in the left volar wrist and arose from the median nerve at its entry point under the ligament. Only a partial excision was performed, effectively decompressing the nerve and providing relief of her symptoms. The 10th case reported by Wood in 1980 was in a 13-year-old child and presented as a subcutaneous mass over the anterolateral aspect of the right distal tibial region. Again, only partial resection of the tumor was done using operative microscope for the first time, and the nerve was preserved.[11] Thus our case represents the 11th patient since the initial report by Sato in 1913.

Case Report

TB is a 43-year-old athletic female seen by one of us for the evaluation of a lump in her left upper inner arm that had been discovered by the patient two months earlier during self-breast examination. She saw several physicians, each ordering numerous studies. These included a physical examination, blood profile, chest films, pelvic examination with ultrasound of the pelvic stuctures, HIV testing, and specific laboratory studies for evaluation of a presumed lymphadenopathy (even though the lesion was not located within the anatomical confines of the axillary lymph node basin). All test results were unremarkable. A trial with antibiotics had also been unsuccesful. On 12 June 1995 she presented to us with a 1.5cm mass located in her right medial upper arm. It was close to the inferior border of the axilla yet clearly outside of it. A Tinel sign was present. An magnetic resonance imaging (MRI) outlined a 1.5 cm well circumscribed mass, intense in T_1 weighted images, and hyperintense in the T_2 weighted

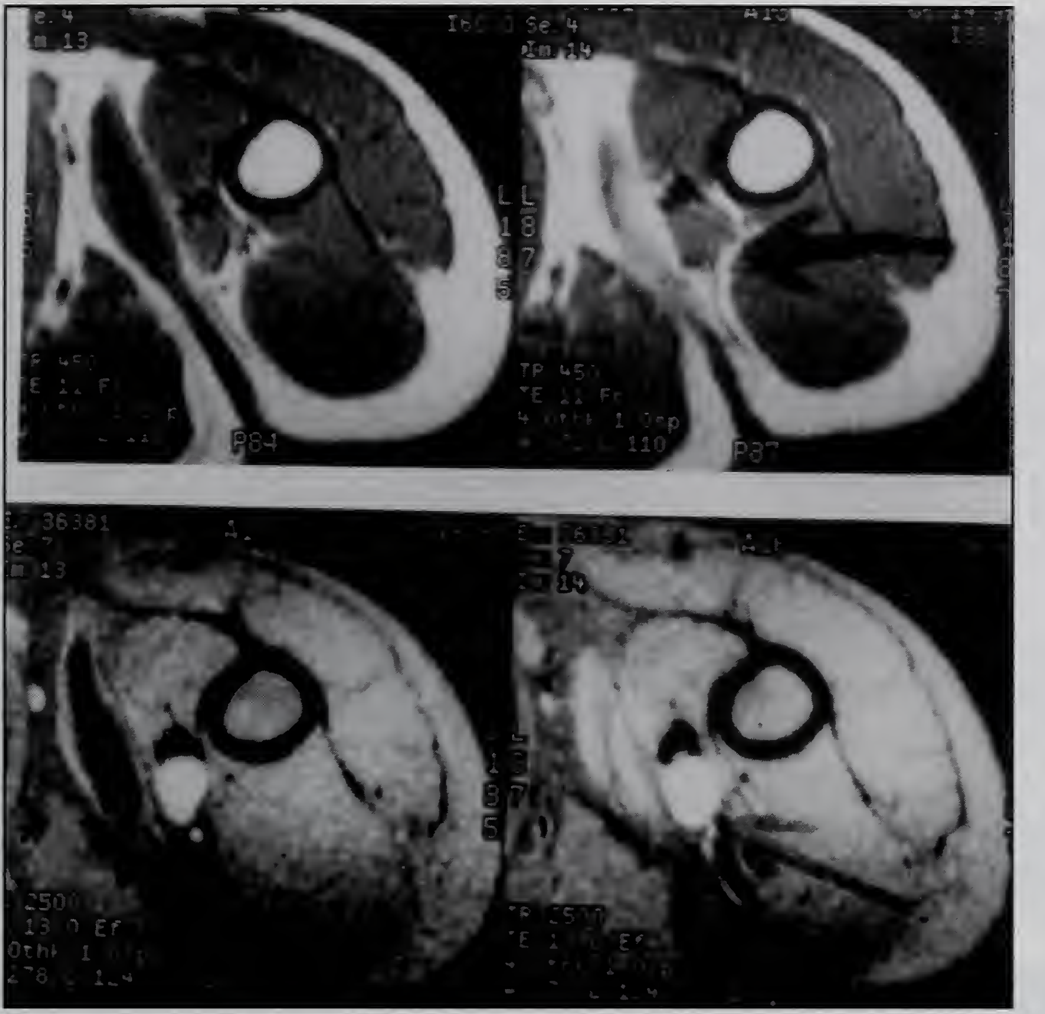

Figure 1.—*Top row:* Two views of MRI, right upper arm. T_1 weighted images of the lesion/arrow). *Bottom row:* T_2 weighted images showing hyperintese appearance of tumor in the same sequences (arrow).

sequences (Fig. 1), suggesting a vascular rather than solid origin. The relationship of the adjacent neurovascular structures of the brachial plexus was not entirely clear but the mass was close to the median nerve at that location. Surgical exploration revealed a blue mass that appeared to be arising from the median nerve, which otherwise appeared completely normal proximally and distally.

The remaining structures, ulnar and musculocutaneous nerves and the brachial artery, and the vein were uninvolved in the lesion (Fig.2). The nerve fasciles were streched over the mass and were moderately adherent to it. The tumor arising from within projected asymmetrically from the medial border of the nerve (Fig.3). The entire appearance was one of a vascular tumor. The near-complete removal of the lesion was accomplished under magnification preserving the integrity of the nerve fascicles. The volume of the specimen was about 20% of the original size, as blood was expressed during removal. Microscopic examination confirmed the diagnosis of benign cavernous hemangioma. The patient exhibited no neurological deficit postoperatively. To date there have been no recurrence or symptoms.

Discussion

The rarity of this entity does not allow any statement regarding age, sex, incidence, or its anatomical preferences. However several comments may be made relative to their management that could be useful. Unless their intraneural origins are recognized, misdiagnosis may lead to nerve injuries. It is important to consider this diagnosis when one is confronted with masses along the location of the major peripheral nerves.

This is particularly important when there are no neurological findings that could lead the examiner toward this possibility. The MRI appears to be an excellent diagnostic tool in evaluating these blood containing tumors. It is also helpful in differention from more commonly encountered primary nerve tumors such as schwannomas, neurofibro-

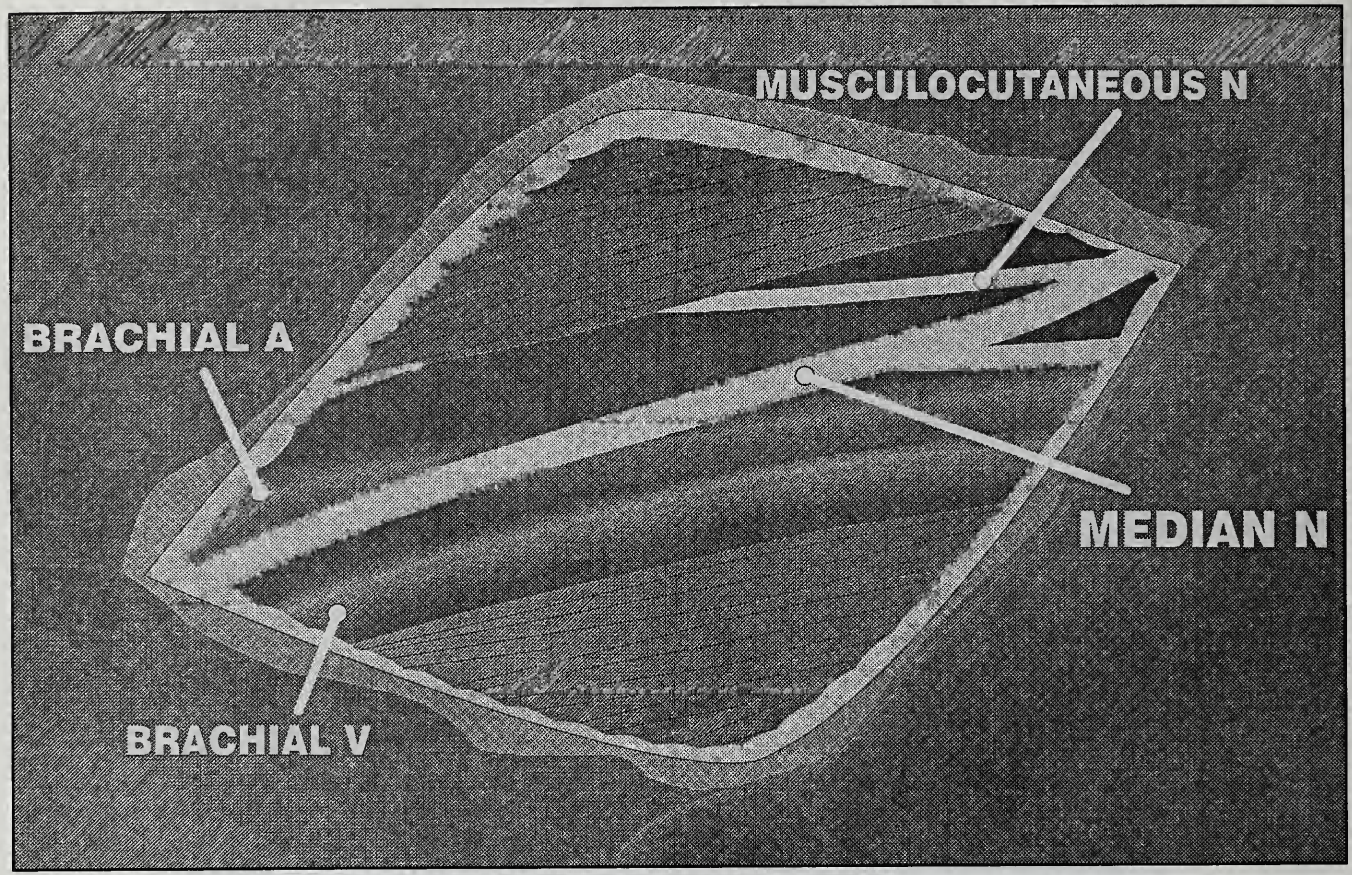

Figure 2.—Anatomical appearance of the operative field. (Artist's drawing)

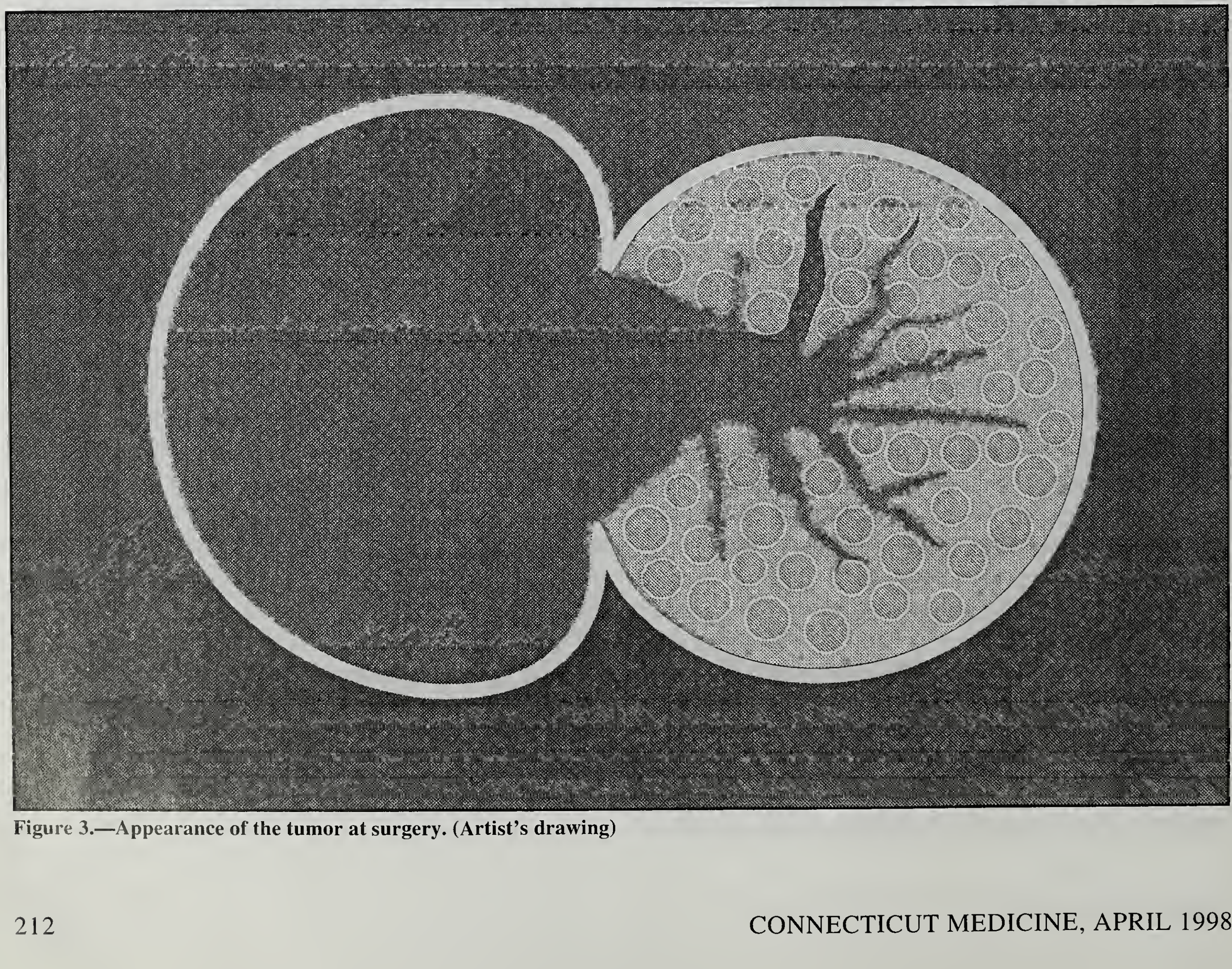

Figure 3.—Appearance of the tumor at surgery. (Artist's drawing)

mas, etc. Soft tissue sarcomas, synovial sarcomas, or ganglions should also be included in the differential diagnosis. This is especially true when the lesion in question is located near a joint. Angiograms, which are useful in the management of soft-tissue malignant tumors for either surgical or intra-arterial chemotherapeutic considerations, are not helpful since contrast material is unlikely to fill these tumors through any microscopic communications, if such communications exist at all. This question has been extensively studied by Ribbert who was unable to find any vascular communications.[11] Furthermore the presence or absence of such microscopic communications may be of no practical value. Malignant tumors of vascular origins, such as hemangiopericytomas or angiosarcomas, are more difficult both to diagnose and differentiate pre- or intraoperatively from their benign counterparts. These considerations make the intraoperative differentiation with the frozen section interpretations a difficult task. Therefore, when necessary a biopsy should be obtained with what can be excised safely without damaging the nerve fascicles. Deferring the definitive treatment to a more thorough histopathological study appears to be more appropriate rather than sacrificing the function of the extremity based on frozen section diagnosis alone. While it is desirable to remove as much tumor as possible, particularly to relieve whatever nerve compression may be present, it is unnecessary to remove all parts of these benign lesions in order to achieve palliation. This is true even when nerve deficit is present, as seen in lesions of long standing, since relief of pressure may be quite sufficient to restore some if not all of the nerve function in time. The preservation of neural function is a far more important consideration in the management of any benign tumor. This is amply supported by the literature, however sparse it may be.

Summary

Important diagnostic and therapeutic challenges confront the surgeon faced with the possibility of an intrinsic hemangioma in a peripheral nerve. A thorough anatomical knowledge of the region and being aware of this particular subgroup, combined with a recognition of the overall benign histopathological characteristics, will help in planning the proper approach to pre- and intraoperative management. In the preoperative stage, a general work up, an MRI, or perhaps a CAT scan of the region are probably the only helpful studies in diagnosing these tumors and in evaluating the relationships between important local structures. Needle biopsies should be avoided. Intra-operatively, the surgeon must rely on several essential ingredients in minimizing if not eliminating the risk of damage to the nerve fascicles with the resultant severe loss of function:

- The use of magnification techniques
- Recognition of the benign character of these tumors
- Avoidance of radical resections based upon frozen section interpretations
- Awaiting full histological results to determine definitive therapy

These steps are prerequisites to proper operative planning to avoid irrepapable damage to the peripheral nerves. Unfortunately this type of operative nerve damage is not an infrequent occurence.

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Monitoring Clinical Quality in Medicaid Managed Care

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COLLEEN M. GROGAN, Ph.D., AND MARIE ROBERTO, Dr.P.H.

ABSTRACT—With the recent exponential growth in managed-care plan enrollment by Medicaid beneficiaries, a variety of quality monitoring systems have emerged. This paper argues that existing quality monitoring systems, originally designed for use by employers in the private sector, are a useful starting point for quality monitoring in the Medicaid program, but that substantial enhancements are needed to provide adequate quality assurance for Medicaid beneficiaries. This paper describes the development of a range of indicators for monitoring the clinical aspect of the quality of care for Medicaid beneficiaries and offers a framework for adapting existing monitoring systems to the needs of the Medicaid population. This work is part of a larger collaborative effort by the Connecticut Department of Public Health and the Department of Epidemiology and Public Health of Yale University School of Medicine to develop a blueprint for state government's role in quality assessment and performance management for managed care.

Introduction

IN the last several years, enrollment in managed-care plans by Medicaid beneficiaries has grown exponentially. Since 1991, enrollment has increased by approximately 450%, with nearly 11 million Medicaid beneficiaries currently enrolled in managed-care plans.[1] States transitioning Medicaid programs to managed care face an immediate obligation to ensure that the care delivered to these populations in the managed-care setting is adequate. This paper describes the development of a range of indicators for monitoring the clinical aspect of the quality of care for Medicaid beneficiaries in the managed-care setting. The research represents the collaborative effort of the Connecticut Department of Public Health and the Department of Epidemiology and Public Health in the Yale School of Medicine to develop a blueprint[2] for the state government's role in quality assessment and performance improvement for managed care.

With over half of the American population now enrolled in managed-care plans, a myriad of systems for monitoring health plan performance has emerged. Some of these systems have been developed in the public sector, most notably the Quality Assurance Reform Initiative (QARI)[3] sponsored by the Health Care Financing Administration (HCFA); others have been developed primarily in the private sector, most notably the Health Plan and Employer Data Information Set (HEDIS)[4,5] sponsored by the National Committee for Quality Assurance (NCQA).

HEDIS, the most prominent of quality monitoring systems, was first released by NCQA in November 1993. Although there is a version of HEDIS designed specifically for Medicaid populations (Medicaid HEDIS),[4] the most recent version of HEDIS (HEDIS 3.0)[5] is purported by NCQA to be relevant for both privately-insured and Medicaid populations. Developed by a broad-based committee which drew members reflecting private and public purchasers, consumers, organized labor, medical providers, public health officials, and health plans, HEDIS 3.0 measures health plan performance in eight domains: 1) effectiveness of care (ie, the achievement of quality care

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processes and outcomes), 2) the accessibility/availability of care, 3) patient satisfaction with care, 4) cost of care, 5) stability of the health plan, 6) effectiveness in informing patients about health care choices, 7) use of services, and 8) health plan descriptive information (ie, standardized descriptions of network, clinical, and risk-management activities).[4] While each of the eight domains of HEDIS may be important for measuring overall health plan performance, this paper focuses on quality of care, or what HEDIS 3.0 entitles "effectiveness of care."

The expedient approach for states designing a quality monitoring system for Medicaid managed care is to adopt HEDIS as a standard instrument for monitoring quality of care. HEDIS, which has been described as the state of the art in health plan performance measurement,[6] has several advantages. Many health plans already collect and report data for HEDIS indicators for their private purchasers. Therefore, reporting these data to states for the health plans' Medicaid enrollees is unlikely to meet substantial resistance from plans. Further, at a time when states are developing more comprehensive regulation of the managed-care industry, having a previously developed and tested tool for one aspect of such regulation, quality assurance, may provide some comfort to legislators and program administrators.

However, critics of HEDIS have described a number of its limitations. HEDIS depends substantially on administrative data, typically claims data,[7] which can mask subtle but clinically significant aspects of care.[8] In addition, HEDIS measures do not adequately adjust for prevalence and severity of disease, factors which may affect HEDIS measures importantly.[9,10] Finally, HEDIS omits important measures[6,9,11] which may be central to the care of specific populations.

Methods

The Connecticut Department of Public Health and the Yale University team of researchers sought an approach that builds on the advantages of HEDIS, while also addressing some of its weaknesses. The methodology used to identify a range of quality indicators for monitoring the quality of care under the Medicaid program was threefold. First, available clinical guidelines and practice parameters published by professional associations and federal agencies were compiled and reviewed. Practice guidelines were compiled from the *Health Standards 1995 Official Directory*[12] as well as from policy statements of the Agency for Health Care Policy and Research (AHCPR), and a number of peer-reviewed journal research articles defining accepted practice standards. From this literature, a preliminary list of quality indicators for

Table 1.—Well-care Quality Indicators

Quality indicator	Medicaid HEDIS	HEDIS 3.0	Proposed System
Childhood immunization	Required	Required	Required
Well-child visits in first year of life	Required		Required
Lead screening			Required
Adolescent immunization		Required	Required
Child and adolescent well-care visits	Required		Required
Substance counseling for adolescents	Required		Required
Smoking cessation counseling for adolescents and adults		Required	Required
Initial prenatal visit	Required	Required	Required
Low birthweight	Required	Required	Required
Post-partum visit	Optional	Required	Required
Cervical cancer screening	Required	Required	Required
Breast cancer screening	Optional	Required	Required
Glycohemoglobin level	Required		
Ambulatory follow-up after admission for mental health disorder	Required	Required	Required
Adult health examinations			Required
Adult dental visits	Optional		
Flu shots for elderly and high-risk groups		Required	Required
Self-reported health of seniors		Required	Required

which there was adequate consensus concerning clinical practice was developed. Second, a group of eight physician experts representing a range of clinical practice, including primary and specialty care, were consulted about quality indicators. Based on both the review of existing practice guidelines and the in-depth expert interviews, a comprehensive list of quality indicators was created. Finally, the steering committee for the project which included an expert team of policy analysts, clinicians, and epidemiologists prioritized the indicators for inclusion in the proposed quality monitoring plan.

The researchers used the following framework for developing quality indicators. Three categories of indicators were developed: well-care indicators pertinent to the general population, disease or condition-based indicators pertinent to the general population, and indicators for special populations. Criteria for adopting quality indicators within each category were three-fold. First, the disease or condition (either being prevented or treated) must be prevalent (either in the general population or a specific population). Second, the disease or condition must be clinically significant; that is, it must have important health consequences for individuals. Third, the disease or condition must be either preventable or treatable by generally agreed upon medical practices. Quality indicators which met these criteria in each category were then prioritized based on the degree to which managed care might be expected to provide low-quality care for such diseases, conditions, or populations.

Results

Tables 1–3 display the comparison of our proposed indicators with the Medicaid HEDIS and HEDIS 3.0 indicators of quality of care. The tables are organized according to indicators of the quality of well-care (Table 1), disease- or condition-based care (Table 2), and care for vulnerable, or special, populations (Table 3). The indicators displayed represent examples of measures found by our process to be central for the clinical care for Medicaid beneficiaries.

Comparisons of our proposed system with the existing HEDIS systems reveal several results. First, most of the well-care indicators (Table 1) in our proposed system are consistent with the most recent version of HEDIS (HEDIS 3.0). The exceptions are lead screening, substance counseling for adolescents, and child, adolescent, and adult health examinations. Medicaid HEDIS requires some of the proposed indicators but omits others, such as smoking cessation and adolescent immunizations, both of which are central to our proposed system of quality monitoring.

Table 2.—Disease or Condition-based Quality Indicators

Quality Indicator	Medicaid HEDIS	HEDIS 3.0	Proposed System
Pediatric care			
Appropriate medication for asthma		Required	Required
Treatment of ear infections		Required	Required
Inpatient admissions for asthma	Optional		Required
Emergency department visits for asthma			Required
Return visits for children with failure to thrive			Required
Maternal care/women with gestational diabetes			
Low birthweight			Required
C-sections			Required
Neonatal intensive care admissions			Required
Maternal care/women with toxemia			
Eclampsia			Required
Seizures			Required
C-sections			Required
Adults with diabetes mellitus			
Diabetic retinopathy screening	Optional	Required	Required
Adults with mental health disorders			
Ambulatory follow-up after hospitalization	Required	Required	Required
Adults with hypertension			
Blood pressure checks >3 times per year			Required
Adults with myocardial infarction			
Beta-blocker use after heart attack		Required	Required

Second, in terms of indicators for care of individuals who have specific diseases or conditions, both Medicaid HEDIS and HEDIS 3.0 are very sparse. As shown in Table 2, Medicaid HEDIS has only one required disease-based quality indicator, and this indicator has been criticized for its lack of correlation with other important mental health outcomes.[11] HEDIS 3.0 has only five disease-based quality indicators, and only two which are relevant to women and children, representing a substantial portion of welfare recipients. The proposed system includes indicators for the more common and clinically significant maternal and child health medical problems: asthma, gestational diabetes, and toxemia.

Finally, neither Medicaid HEDIS nor HEDIS 3.0 include indicators for vulnerable populations who, due to their substantial health needs and limited resources to negotiate and access needed medical care, are likely to be at risk for poorer treatment in a managed-care setting. In contrast, the proposed system identifies foster children, children born to HIV-infected mothers, and the chronically mentally ill as vulnerable populations. For each of these populations, a set of indicators is recommended (Table 3).

Discussion

The analysis suggests that, although both Medicaid HEDIS and HEDIS 3.0 are useful starting points for quality monitoring, substantial enhancements are needed to provide adequate quality assurance for Medicaid managed-care programs. Specifically, both Medicaid HEDIS and HEDIS 3.0 lack important indicators in the areas of well-care, disease- or condition-based care, and care for vulnerable populations.

Within the area of well-care, the proposed inclusion of lead screening is consistent with literature showing a strong association between elevated blood lead levels and minority ethnicity, lower incomes, and lower educational levels,[13,14] all factors which are more prevalent among Medicaid beneficiaries than in the general population. The recommendation to include substance counseling as a quality indicator reflects evidence of increased substance use among welfare recipients, relative to the general population.[15] Further, monitoring the frequency and nature of well-child, adolescent, and adult health examinations is especially important given the evidence of lacking primary-care access for poor, publicly-insured individuals.[16–17]

Even more apparent is the limited range of care for specific diseases or conditions for which HEDIS has quality indicators. The majority of quality indicators pertain to well-care and prevention efforts. Prevalent and clinically significant conditions in the area of maternal and child health, central to the medical care for many Medicaid beneficiaries, are not included in HEDIS.

Finally, because the HEDIS measures were designed to monitor the care of a privately-insured population, many of the vulnerable populations for whom the state is responsible are not represented. The importance of targeting vulnerable populations for quality monitoring in managed care is highlighted by several empirical reports demonstrating that poorer individuals and individuals with chronic illnesses experience differentially worse outcomes in managed-care settings than individuals of the general population.[18,19] The omission of quality indicators for such populations is particularly problematic since they may be less able than the general population to detect poor quality

Table 3.—Quality Indicators for Special Populations

Quality Indicator	Medicaid HEDIS	HEDIS 3.0	Proposed System
Foster Children			
Physical examinations first year of placement			Required
Mental health examinations first year of placement			Required
Children Born to HIV-infected mothers			
HIV culture of PCR			Required
CD4 count and percentage			Required
AZT administration			Required
Bactrim administration			Required
PCP prophylaxis			Required
Chronically mentally ill			
Contact with health provider every six months			Required
AIMS tests for neuroleptic dose monitoring			Required
Lithium blood levels every six months			Required
Ambulatory follow-up after hospitalization			Required

care when it is delivered and less able than privately-insured individuals to switch away from unacceptable plans and providers. Existing quality monitoring systems have limited means to track or detect these aspects of quality of care.

Although individuals represented by these populations require preventive health care as the general population does, additional medical care interventions may be necessary due to the "high-risk" nature of such individuals. For example, although children placed in foster care benefit from the routine care recommended for all children, their experiences prior to placement put them at increased risk for developing emotional and behavioral problems. Even though practice guidelines[20] require routine developmental and behavioral screening, if pediatric medical care providers in managed-care plans with Medicaid beneficiaries are not trained in the recognition of such problems, they may go undetected and under-treated or poorly treated. The proposed system addresses this significant omission by identifying examples of vulnerable populations and a set of quality indicators for each.

We believe this analysis offers a reasonable framework as well as a range of specific quality indicators for guiding the state in developing a quality assurance system for care delivered under the Medicaid managed-care program. However, the proposed system should be assessed within the context of its limitations. The process used to develop indicators does not reflect the experience of a random sample of clinicians or researchers but rather a range of expert opinions. This process of relying on selected expert opinions is not unlike that used by the Agency for Health Care Policy and Research in its development of clinical guidelines,[21] but may limit the representativeness of the proposed indicators. Additionally, the proposed indicators are at the earliest stages of development and would require substantial additional refinement related to their measurement and specification prior to implementation.

Conclusion

Despite the widespread use of managed care and its adoption by several state Medicaid programs, little is known about its impact on quality of care, especially for Medicaid beneficiaries. The literature generally concludes that managed care is associated with cost savings in the range of 5% to 15% over the fee-for-service system.[22-24] Although reports concerning access[23,25,26] and quality of care[18,19,27] remain equivocal, there is a growing consensus that poor and chronically ill patients are at the greatest risk for inadequate access and poor quality in the managed-care setting.[27] Based both on these results and the accelerating growth of enrollment of Medicaid beneficiaries in managed-care plans, quality monitoring is an essential component of the transition to managed Medicaid.

Many states are now adopting a variety of ways for judging health plan performance more broadly, including measures of consumer satisfaction, medical loss ratios, and stability and scope of physician networks. Despite the breadth and sophistication of these measures, adequate indicators of the fundamental aspect of health plan performance, the quality of care, remain elusive. HEDIS is a favored approach for monitoring quality in managed Medicaid due, in part, to its prominence and acceptability in the private market. Given the broad base of support for HEDIS as well as its careful attention to issues of measurement and scientific soundness, HEDIS is a reasonable place to start. However, our experience suggests substantial omissions from the HEDIS framework that should be addressed in its adoption by states for monitoring quality in managed Medicaid programs. Additional indicators targeted at the unique health needs of the Medicaid population in each state should be included in any comprehensive quality monitoring system. These indicators must be sensitive to not only well-care and disease-based services of the general population, but also specific health needs of vulnerable populations which may otherwise be at increased risk for poor outcomes in the managed-care setting. Given the fundamental obligation of states to protect vulnerable populations, states must work to design quality indicators that address the health-care services which are central to the lives of such individuals.

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Ongoing Physician Guidance to Achieve Periodic Mammography of Women at an Urban Health Center

DAVID I. GREGORIO, Ph.D., M.S., ELLEN O. NESTLER, M.D., BRUCE GOULD, M.D., AND DEBORAH PATURZO, M.S.

ABSTRACT—The use of a low-cost behavior prompt at an urban, hospital-based health center that encourages physicians to record and act upon cancer screening information is described. Brief audit forms were incorporated into medical records of all women 40+ years of age seen between June 1994 and March 1996 (approximately 4,700 office visits). Audit forms alerted physicians about women's breast and cervical cancer screening histories and encouraged them to note any screening done or recommended during an office visit. Patient attributes did not readily distinguish who was and was not screened with mammography at recommended intervals, nor whether physicians did or did not address those needs for examination. On the other hand, explicit, continuous monitoring in medical records of the cancer screening status of women was associated with outcome variables. Availability of information on prior cancer screening activities significantly increased the odds that women were "on-time" for examinations as well as that physicians addressed the needs of women who were "past due" for mammograms at the time of their office visits.

Introduction

AGE-ADJUSTED breast cancer death rates could be reduced by 9.5% (accounting for roughly 4,000 lives annually) through greater reliance on clinical preventive services.[1] Periodic screening by mammography in combination with clinical breast examination (CBE) is warranted, as is monitoring the familial breast cancer histories of individuals.[2-5] Unfortunately, however, mammography is delivered at a pace will below the optimal level.

Regardless of individual beliefs and circumstances that deter some women from having mammograms (eg, concerns about availability, access, cost, and quality of services, along with fears and misunderstandings about cancer and its early detection), women who receive explicit recommendations from their physician about mammography are more likely than others to undergo examinations.[6-9] When questioned about why they have not had a previous or recent mammogram women often reply, "My doctor has not mentioned that I need one," and conversely, when asked their reason for being screened women typically respond, " My doctor told me I should have an exam."

The dissemination of clinical practice guidelines, in itself, cannot assure that physicians will increase their attention to delivery of preventive services.[10,11] On the other hand, explicit efforts to prompt behavioral change in physicians by the use of memory aids such as checklists, tickler files, records flags, and the like, have been successful.[12-14] This paper describes a 22-month project to implement a clinical tracking and reminder system around the delivery of cancer screening services for low-income women who received health services at an urban, hospital-based health center. As part of a cooperative agreement with the Centers for Disease Control (CDC) to build

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technical capacity within Connecticut for a comprehensive breast and cervical cancer screening program, a system to monitor clinical performance of physicians and encourage their providing preventive services was built and field tested over a 22-month period (June 1994 to March 1996). Our analysis corroborates earlier findings about the importance of physician guidance to women's decisions to have periodic screening mammograms. Ultimately, the findings relate counseling of patients by the physician during those encounters to the subsequent act of obtaining a mammogram. Three related questions were addressed: 1) What differentiated women who at the baseline of this study were "on-time" for screening mammography from those who were "past due"? 2) What factors were associated with physician efforts to address the need for mammography screening of woman who were "past due"? and 3) What distinguished women who followed physician recommendations to be examined from those who did not?

Methods

A brief clinical encounter form (Appendix A) was developed for attachment to a woman's medical record so that her physician could rapidly determine the current status of her breast and cervical cancer screening. The form was intended for multiple purposes. Its bright color and placement atop the medical record provided physicians an explicit cue to action. The form's instructions reiterated the clinic's protocols regarding periodic Pap testing, clinical breast examinations, and mammography (as well as counseling about breast self-examination) which provided normative standards to which physicians could model their behaviors. Furthermore, information recorded on the form highlighted the adequacy of the medical record regarding prior cancer screening to allow physicians to self-monitor their capacity to deliver *and document* clinical preventive services. Finally, it provided data entry fields for physicians to affirm that cancer screening was addressed during an office visit.

Beginning in June 1994 and continuing through April 1996, encounter forms were attached to medical records of all women scheduled for office visits. During that time, 3,014 women *scheduled* appointments for medical or gynecological services at the facility and 2,111 women *completed* at least one scheduled office visit. Of that latter group, 962 individuals were 40+ years of age. It is the compliance of women whom the clinic targeted for periodic mammography screening and the performance of the clinic's attending and resident physicians caring for them (accounting for roughly 4,700 office visits), that are the foci of this research.

Just prior to the first occasion during the project period when a woman was scheduled to be seen, a brief audit of her medical record was completed by project staff who sought explicit information about a familial history of breast cancer (either positive or negative) and dates of the woman's most recent Pap test, CBE, pregnancy, and mammogram. This audit was intended to facilitate, but not substitute for, physician inquiry about a woman's current cancer screening status. Information from the audit was recorded on the encounter form and data fields for missing or ambiguous information were highlighted so that physicians could review the record and question the patient during her visit.

The encounter form instructed physicians to note by simple check marks for each procedure (eg, Pap testing, CBE, and mammography) that the service was delivered or recommended during the visit, the woman was referred elsewhere for that service, the service was recommended without further action taken, or no action was taken or recommendation made because screening was not indicated at the time. At the completion of an office visit, encounter forms were removed from medical records and data were transferred to the project's electronic data file. At any subsequent office visit by that woman, the electronic data file was scanned and a new encounter form with up-to-date medical records and screening information was prepared for use by physicians.

Our analysis examined three sequential outcomes; the woman's baseline mammography screening status, activity by a physician when patients were "past due" for examination, and the subsequent response of women to physician efforts to have her screened. A woman's baseline mammography screening status was determined as of her first scheduled appointment during the project period by comparing the number of months that had elapsed between the appointment date and the date of her last mammogram. A woman was considered to be "on time" if she was 40 to 49 years of age and had had an examination within 30 months, or if she was over age 50 and had had a mammogram within 18 months. Otherwise, she was considered for this analysis to be "past due" for mammography screening.

Among women who were "past due" for examinations (n=487), a physician's response was characterized according to notations made on the encounter form. *Any notation* on an encounter form by a physician indicating that a woman had been counseled, had been referred elsewhere, or that screening was not indicated was interpreted for our purpose that mammography screening was addressed by the physician; absence of notation on the encounter form during the entire project period was interpreted to mean that the mammography screening for that woman *was never addressed* by the physician. Because patients completed, on average, more than four office visits during the project period, physicians had multiple opportunities to address mammography screening for women who needed examinations.

The effect of having been counseled about the need for a mammogram was evaluated according to whether the medical records of women who were initially "past due" for screening subsequently included a report that the procedure had been completed. Typically, screening was done through the nearby affiliated hospital's radiology department or its mobile van which schedules infrequent visits (two-to-four annually) to the health center.

Outcomes (ie, being "on time" for screening, addressing a woman's need for screening, and obtaining a mammogram) were evaluated in relation to patient and provider attributes, the content of the medical record, and notation by physicians on encounter forms. Nominal measures were used to distinguish patients by age (40 to 54 years, 55 to 69 years, 70+ years), race (African American, other), marital status (married, other), and source of payment for care (Medicaid/Medicare, other). Providers were distinguished according to the clinic within which they practiced (general medicine, obstetrics/gynecology).

Crude odds ratios and 95% confidence intervals are reported which estimate the likelihoods, respectively, that women were "on time" for screening at baseline, that a physician ever addressed need for screening of "past due" women during the project period, and that women subsequently completed recommended mammography examinations.

Results

At baseline, 475 of the 962 women in this analysis (49%) were considered to be "on time" for mammography screening. By our criteria, physicians addressed the need for screening mammography with roughly one-half of those women who were "past due" for examinations (266/487=55%). A total of 146 mammograms were provided during the project period, meeting the need for screening of 30% of women who were "past due" for examinations at baseline.

The comparison of women who were "on time" at baseline with those who were "past due" for mammograms is presented in Column A of Table 1. Our analysis did not

Table 1.—Odds ratios (with 95% confidence intervals) that mammography screening was on time, addressed during visit, and completed after visit among women 40+ years of age seen at a hospital-based health center.

	Odds ratio that screening was		
Patient Attributes	**"on time" (n=962)**	**addressed (n=487)**	**completed (n=266)**
55-69 years *vs* 40-54 years	1.31 (0.98 - 1.74)	1.41 (0.92-2.15)	1.62 (0.91-2.88)
70+ years *vs* 40-54 years	0.96 (0.64 - 1.44)	0.68 (0.39-1.19)	1.82 (0.79-4.16)
African American *vs* other	0.79 (0.61 - 1.03)	0.98 (0.63-1.51)	0.54 (0.32-0.92)
Married *vs* other	0.96 (0.70 - 1.32)	1.08 (0.68-1.70)	1.28 (0.69-2.39)
Public payer for care *vs* other	1.40 (0.91 - 2.18)	0.98 (0.55-1.74)	2.62 (1.35-5.15)
Medical Specialty of Provider			
General medicine *vs* OB/Gyn	1.29 (0.93 - 1.78)	1.91 (1.21-3.15)	0.84 (0.43-1.65)
Baseline information on prior cancer screening			
Pap screening history	—	2.99 (1.93-4.64)	1.38 (0.67-2.85)
Clinical breast examination history	—	2.82 (1.82-4.39)	0.56 (0.26-1.02)
Mammography history	—	4.28 (2.82-6.52)	1.43 (0.73-2.86)
Current cancer screening noted on clinical encounter form			
Pap screening addressed during visits	—	—	0.87 (0.40-1.88)
Clinical breast examination addressed during visits	—	—	0.75 (0.35-1.58)
Breast self-examination addressed during visits	—	—	0.80 (0.44-1.51)

differentiate groups according to the age, race, or marital status of women, nor how care was paid for or the specialty of the physician treating them. None of those crude odds ratios statistically differed from 1.0.

We next examined instances where patients were "past due" for examination and estimated the relative odds that a physician would explicitly address that need at some time during the project period (Column B). For those 487 women who were "past due" at enrollment, the odds that screening mammography was subsequently addressed did not differ according to patient age, race, marital status, or how they paid for care. We did find that physicians working in the general medicine clinic were nearly twice as likely as those in the OB/GYN clinic (OR = 1.91) to address mammography during visits.

The odds that physicians addressed a woman's need for a mammogram was significantly greater if the medical record *at baseline* contained information about prior cancer screening activity. Documentation specific to mammography, even if the record explicitly noted no prior examinations, increased odds of a subsequent recommendation 4.28-fold, while information about prior Pap testing increased odds by 2.99, and information about CBE by 2.82.

Finally, we reviewed the records of women who were counseled by physicians about their need for mammograms (n=266) to differentiate those who subsequently obtained examinations from those who did not heed physician recommendations. That analysis (Column C) found only two factors to affect significantly the likelihood that screening was done. Among women who were counseled by a physician, African American women were only 54% as likely as all others to have gone on for screening, while patients who were on public assistance were 2.62 times more likely than others to be examined. No other factor distinguished groups.

Discussion

Many women are in need of periodic mammography and a sizable portion of them may not be regularly advised by physicians about the importance of being screened. In this study of women who receive health care at an urban, hospital-based health center, roughly one-half (51%) were "past due" for screening examinations at baseline and a comparable proportion (45%) did not have that need for a screening examiantion addressed by physicians during subsequent office visits.

We found that patient attributes did not readily distinguish those who were and were not screened with mammography at recommended intervals, nor whether a physician did or did not address the woman's need for examination. On the other hand, our findings suggest that explicit, continuous monitoring in medical records of the cancer screening status of women was associated with outcome variables. Availability of information pertinent to prior cancer screening activities significantly increased the odds that physicians addressed the needs of women who were "past due" for examinations during office visits.

Despite the prospective design used here, we caution readers that any conclusions about causal direction and explanation for these results are tentative. For one thing, it may be that physicians who emphasize delivery of clinical preventive services also are better record keepers. If so, these findings reflect the consequence, rather than cause, for increased mammography screening of women. For another thing, we emphasized the analysis of crude odds ratios that may obscure more complicated causal processes. A preliminary analysis (not reported) did not uncover evidence that patient or provider attributes were related to the content of medical records or encounter forms, yet we cannot disregard a possibility that the notations examined here reflect disparities of how women seek and receive care, or how such care was documented. We believe that notations made by physicians reflect their behavior reasonably well and that errors of omission on encounter forms (ie, failure to document that screening needs were addressed or completed) are few and produce conservative biases that would understate the true underlying association between measures.

Our intervention was intended to focus physicians' attention on the content of medical records to afford them opportunities persuasively to discuss cancer screening with patients. From that perspective, this project offers evidence that the knowledge-performance gap existing between physicians' beliefs about the effectiveness of breast cancer screening and the integration of such beliefs into their routine clinical practices may be lessened by a relatively low-cost intervention that encourages physicians to record and act upon cancer screening information.[14-16]

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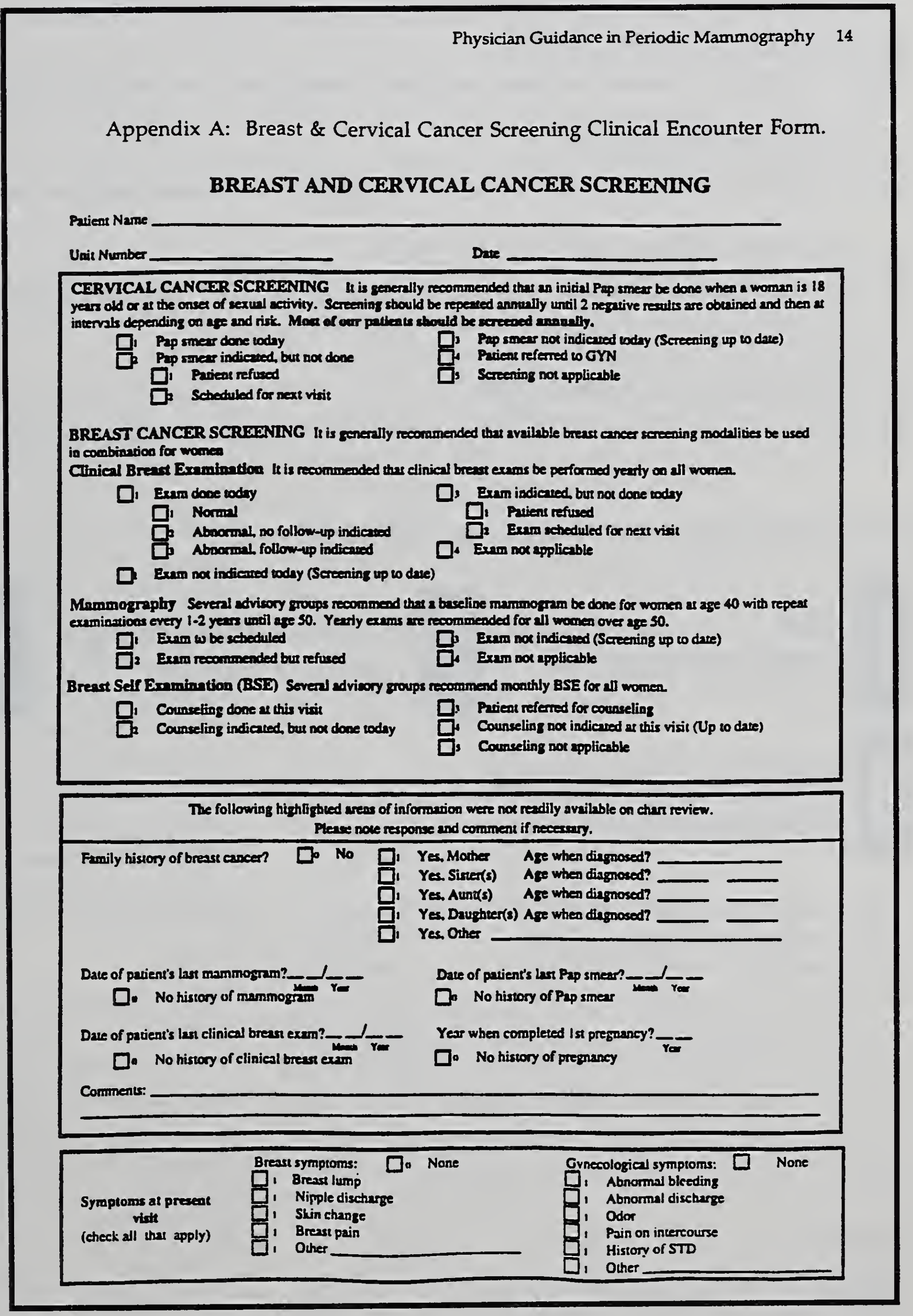

Appendix A: Breast and Cervical Cancer Screening Clinical Encounter Form.

Physician Guidance in Periodic Mammography 14

Appendix A: Breast & Cervical Cancer Screening Clinical Encounter Form.

BREAST AND CERVICAL CANCER SCREENING

Patient Name ______________________________

Unit Number ____________ Date ____________

CERVICAL CANCER SCREENING It is generally recommended that an initial Pap smear be done when a woman is 18 years old or at the onset of sexual activity. Screening should be repeated annually until 2 negative results are obtained and then at intervals depending on age and risk. **Most of our patients should be screened annually.**

- ☐1 Pap smear done today
- ☐2 Pap smear indicated, but not done
  - ☐1 Patient refused
  - ☐2 Scheduled for next visit
- ☐3 Pap smear not indicated today (Screening up to date)
- ☐4 Patient referred to GYN
- ☐5 Screening not applicable

BREAST CANCER SCREENING It is generally recommended that available breast cancer screening modalities be used in combination for women

Clinical Breast Examination It is recommended that clinical breast exams be performed yearly on all women.

- ☐1 Exam done today
  - ☐1 Normal
  - ☐2 Abnormal, no follow-up indicated
  - ☐3 Abnormal, follow-up indicated
- ☐2 Exam not indicated today (Screening up to date)
- ☐3 Exam indicated, but not done today
  - ☐1 Patient refused
  - ☐2 Exam scheduled for next visit
- ☐4 Exam not applicable

Mammography Several advisory groups recommend that a baseline mammogram be done for women at age 40 with repeat examinations every 1-2 years until age 50. Yearly exams are recommended for all women over age 50.

- ☐1 Exam to be scheduled
- ☐2 Exam recommended but refused
- ☐3 Exam not indicated (Screening up to date)
- ☐4 Exam not applicable

Breast Self Examination (BSE) Several advisory groups recommend monthly BSE for all women.

- ☐1 Counseling done at this visit
- ☐2 Counseling indicated, but not done today
- ☐3 Patient referred for counseling
- ☐4 Counseling not indicated at this visit (Up to date)
- ☐5 Counseling not applicable

The following highlighted areas of information were not readily available on chart review.
Please note response and comment if necessary.

Family history of breast cancer? ☐0 No
☐1 Yes, Mother Age when diagnosed? ________
☐1 Yes, Sister(s) Age when diagnosed? ____ ____
☐1 Yes, Aunt(s) Age when diagnosed? ____ ____
☐1 Yes, Daughter(s) Age when diagnosed? ____ ____
☐1 Yes, Other ________________

Date of patient's last mammogram? __ __/__ __ Month Year
☐0 No history of mammogram

Date of patient's last Pap smear? __ __/__ __ Month Year
☐0 No history of Pap smear

Date of patient's last clinical breast exam? __ __/__ __ Month Year
☐0 No history of clinical breast exam

Year when completed 1st pregnancy? __ __ Year
☐0 No history of pregnancy

Comments: ________________________________

Symptoms at present visit (check all that apply)

Breast symptoms: ☐0 None
- ☐1 Breast lump
- ☐1 Nipple discharge
- ☐1 Skin change
- ☐1 Breast pain
- ☐1 Other ____________

Gynecological symptoms: ☐ None
- ☐1 Abnormal bleeding
- ☐1 Abnormal discharge
- ☐1 Odor
- ☐1 Pain on intercourse
- ☐1 History of STD
- ☐1 Other ____________

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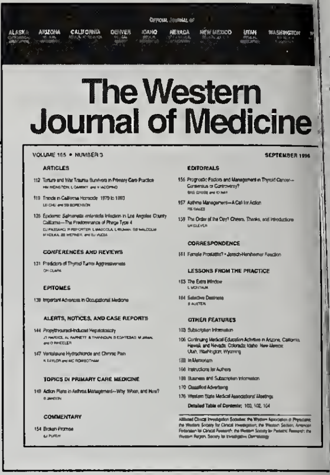

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Important Advances in Clinical Medicine

Allergy and Immunology

Alan Goldsobel, M.D., and Sheldon Spector, M.D., Section Editors

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in allergy and immunology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in allergy and immunology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Allergy and Immunology of the California Medical Association, and the summaries were prepared under the direction of Drs. Goldsobel and Spector and the Panel.

Recommendations for Immunizations in HIV-Infected Individuals

AS the life expectancy of patients infected with human immunodeficiency virus (HIV) lengthens, health-care professionals must give more consideration to prophylaxis against common diseases. Clearly, everyone should receive immunizations that are safe, effective, and clinically relevant, but not all pathogens are unusually virulent or overrepresented in HIV-infected individuals, and a vaccine's safety in this population can be difficult to determine. Live viral vaccines are usually contraindicated in immunosuppressed patients; in addition, the process of immunizing a patient theoretically could promote the activation of latent or controlled HIV infection. Since many HIV-infected patients are immunocompromised and may not mount an appropriate antibody response later in the course of HIV infection, it is important to consider administering vaccines soon after HIV infection when CD4$^+$ T-lymphocyte counts are high and patients are clinically well.

An annual influenza vaccine is recommended for HIV-infected individuals, although patients with advanced disease are unlikely to mount an appropriate antibody response. There is no evidence that influenza is more common or severe in HIV-infected persons, but the vaccine is generally safe and well-tolerated. Hemophilus influenza type B is a problem in HIV-infected children, and the Hib vaccine is therefore recommended for them (and for all children). Since most flu in adults is not type B, its importance in older individuals is less clear, although HIV-infected adults lacking splenic function should receive the Hib vaccine. The vaccine against pneumococcal infection, a malady greatly increased in HIV-infected patients, is recommended, and revaccination is advised every six years. Adverse effects are rare.

The classic primary immunizations of childhood include those against measles, mumps, and rubella. Because these are live, attenuated viral vaccines, their use in symptomatic HIV-infected patients is a potential problem. Asymptomatic, immunologically naive, HIV-infected persons, however, would probably benefit from this vaccination during a measles outbreak. Oral polio vaccine is a live viral vaccine contraindicated in HIV infection, but the inactive form of the vaccine can be administered safely. Tetanus and diphtheria boosters, recommended every 10 years, appear to be safe in HIV infection.

Many HIV-infected persons have been exposed to hepatitis B. Unfortunately, the hepatitis B vaccine has shown a poor response rate in this group. Nonetheless, asymptomatic HIV-infected patients without evidence of antibodies to hepatitis B should receive the three-vaccination series. Interestingly, hepatitis A vaccine is more immunogenic in HIV-infected patients than most other vaccines. Travelers to areas endemic for hepatitis A who have no immunity should be vaccinated with this killed, inactivated viral vaccine.

The recommendations for vaccinations for foreign travel change frequently depending on epidemics, sanitation conditions, and other factors. The live, attenuated yellow

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fever vaccine is contraindicated, but many of the inactivated vaccines may be safe for use in HIV-infected individuals. In general, a careful evaluation of the potential risks and benefits of a given vaccine is always the first step in developing an individual immunization regimen.

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Drug Reactions in HIV/AIDS

ADVERSE reactions to drugs are frequent in patients with human immunodeficiency virus (HIV) infection and AIDS. The most commonly prescribed drug for AIDS patients is trimethoprim-sulfamethoxazole (TMP–SMX); it is also the most common source of adverse reactions. Up to 40% of patients receiving high-dose TMP-SMX develop a maculopapular diffuse rash, often with fever and malaise. Similar reactions have been reported with clindamycin, diapsone, pyrimethamine/sulfadoxine, aminopenicillins, clavulanate, thalidomide, atovaquone, nevirapine, delavirdine, rifampin, probenecid, and 1592 (a new antiviral drug).

The cause of these reactions is not clear. Immunologic processes might be involved, since patients with HIV and AIDS demonstrate immunoactivation as well as immunodeficiency. A polyclonal increase of immunoglobulins (including IgE), increased circulating immune complexes, and an increased number of activated CD8$^+$ cells may be secondary to various infections. Abnormal hepatic metabolism may result in the persistence of drug metabolites that act as antigens or have direct cellular toxicity. Alternatively, an incompetent immune system may fail to clear the metabolites. Finally, incidence of certain viral infections, such as herpes simplex virus, hepatitis B virus, cytomegalovirus, and Epstein-Barr virus (EBV), is increased in patients with HIV and AIDS. These infections may stimulate the immune system, predisposing the patients to drug reactions such as that between EBV and aminopenicillins. There is no conclusive evidence that the incidence of IgE-mediated reactions to drugs, such as penicillin-induced anaphylaxis, is increased in patients with HIV/AIDS. Rather, the incidence of some adverse drug reactions seems to increase with advancing immunodeficiency. A possible participation of hepatic drug metabolism may explain the success of incremental dosing (as with nevirapine and delavirdine) and desensitization protocols in minimizing the problems.

The most common clinical presentation of an adverse drug reaction in patients with HIV/AIDS is rash. The rash, which starts seven to 12 days after initial exposure to the culprit agent, is usually diffuse, erythematous, maculopapular, and pruritic and is frequently accompanied by fever and malaise. Conjunctivitis is common, but mucous membrane involvement is not. Susceptible patients may have identical or nearly identical symptoms from several agents. More severe reactions, such as Stevens-Johnson syndrome, bullous lesions, and toxic epidermal necrolysis, also may occur. Hepatic and hematologic abnormalities can stem from immune-mediated injury or direct toxicity; rare cases have been reported of eosinophilic pneumonia possibly secondary to drugs.

The diagnosis of adverse drug reactions rests mainly on a good history, especially a detailed drug history, timing of introduction of the suspected agent, and clinical symptoms and physical examination.

Withdrawal of the offending agent is usually successful in treating the reactions. Although severe bullous rashes are often treated with corticosteroids, the effects of this treatment are difficult to assess. We have noted remarkable responses to intravenous immunoglobulin infusion in a few seriously ill patients with bullous skin rashes.

Although avoiding the offending agent is the safest method to treat the problem, it may not be the best approach if the agent is the drug of choice and there is no tolerated alternative. In such circumstances, a careful desensitization may be attempted. Desensitization has been successful with TMP/SMX, clindamycin, sulfadiazine, and other agents, but probably should not be attempted for such serious or life-threatening reactions as anaphylaxis, bullous dermatitis, or renal or hepatic failure.

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Latex Allergy—The Latest Insights

URTICARIA to latex has been reported as early as 1927 and more recently in 1979. Fatal reactions to latex-tipped barium enema catheters brought attention to the potentially serious nature of the allergy around 1990. In recent years, awareness of the condition has risen, as has exposure to latex: more than 40,000 products contain latex, and latex gloves are omnipresent in health care settings. As a result, more and more latex-sensitive patients are being identified. Groups reported to have high prevalence rates of latex allergy include health care workers, dental workers, rubber industry workers, housekeepers, spina bifida patients, and patients undergoing frequent catheterizations or multiple surgeries.

Two potential mechanisms for sensitization are common: direct contact and inhalation of aerosol latex proteins carried on the cornstarch of powdered gloves. Latex-sensitive individuals experience symptoms that vary from localized hand symptoms such as itching or urticaria to a wide range of systemic reactions including generalized urticaria, sneezing, tearing, coughing, wheezing, and even anaphylaxis with hypotension shortly after exposure to latex products. Some investigators have noted a progression of symptoms in health care workers from contact dermatitis to localized urticaria to systemic IgE-related symptoms. On the other hand, a significant number of patients who develop systemic IgE symptoms do so without any preexisting contact dermatitis.

In a patient known to have other allergies, it can be difficult to determine whether latex exposure is precipitating symptoms or simply aggravating them. In questionnaires, many people self-report symptoms that could be from latex exposure, but few cases are confirmed by diagnostic tests. Recent epidemiologic studies have reported prevalence rates in health care workers ranging from 2.9% to 17%, but ascertainment bias may be a factor in those results. Better-designed epidemiologic studies as well as longitudinal studies must be undertaken.

The immunologic mechanism for systemic reactions to latex is a type I hypersensitivity mediated by IgE antibodies directed against latex rubber proteins. According to one study, 57 of the 200 proteins in latex bind to human IgE. Seven sensitizing latex proteins have been identified, cloned or partially characterized, and assigned allergen designations of Hev b1–b7 by the International Union of Immunological Societies. A high percentage of patients who are latex sensitive are also positive for at least one food skin test, suggesting epitopes common to both latex and food allergens. Foods that cause allergic reactions in latex-sensitive patients include banana, avocado, kiwi, chestnut, potato, cherry, apricot, papaya, passion fruit, and melon.

Three FDA-approved latex-specific IgE in vitro tests are available: Alastat, CAP, and Hycor. Although these assays claim high sensitivity and specificity, their accuracy and reliability can only be determined with broader clinical experience in various populations. A challenge procedure may be used to clarify the diagnosis in patients who have clinical histories that conflict with skin test or in vitro test results, and developing standardized challenge procedures is an important area of research. There is no standardized skin test reagent—testing patients with extracts of unknown potency has resulted in systemic reactions, limiting the use of skin testing. A multicenter clinical trial using a Food and Drug Administration-approved nonammoniated latex extract is underway.

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Antileukotrienes—1997 and Beyond

ANTILEUKOTRIENES represent a new class of asthma medication. They modulate inflammation, they have a mild bronchodilator activity, and their virtual lack of side effects represents an advantage over many other antiasthmatic compounds. Antileukotrienes have the ability to counter most of the basic pathogenic mechanisms of asthma, and they modify increased vascular permeability and edema formation, increased mucus production, bronchoconstriction, and cellular inflammatory exudate.

Two main classes of agents modulate leukotrienes, the leukotriene receptor antagonists and the inhibitors of key enzymes involved in the synthesis of leukotrienes. The latter class can be divided into two further groups: those that inhibit 5-lipoxygenase [5-LO] and those that inhibit the activity of 5-lipoxygenase activating protein (FLAP). Of the many compounds currently under study, only two agents, zafirlukast and zileuton, have received approval from the Food and Drug Administration (FDA).

The potential usefulness of the antileukotrienes has been demonstrated in various experimental and clinical studies. Their mechanisms vary, suggesting that agents within the leukotriene category should be substituted if clinical response is not adequate. For example, virtually all the receptor agonists improve dose response, and some agents, such as zafirlukast and the FLAP inhibitor BAY 10005, block both early- and late-phase allergen challenges.

Many agents block hyperresponsiveness as measured by methacholine or histamine inhalation challenge. They include the receptor antagonists zafirlukast and pranlukast and the synthesis inhibitors BAY 10005 and MK-886. Almost all of the leukotriene antagonists and inhibitors have been shown to block exercise-induced asthma and cold air challenge to some degree.

It is thought that antileukotrienes might be particularly effective in the subgroup of patients with aspirin idiosyncrasy. The leukotriene antagonist SKF-104353 was shown to be an effective blocker in five subjects studied; similarly, pranlukast in a single dose of 225 mg showed an impressive effect in six aspirin-sensitive patients. A single dose of 750 mg of montelukast blocked an inhaled lysine aspirin challenge in patients with aspirin sensitivity, and zileuton in a dose of 600 mg four times a day for six to eight days also was found to attenuate aspirin challenges and decrease urinary LTE_4 levels. In the latter study, the agent was also found to attenuate nasal, gastrointestinal, and dermal responses to aspirin.

Many researchers have studied antileukotrienes in clinical asthma. For example, compared with baseline measurements, patients receiving 40 mg of zafirlukast experienced a 46% decrease in nighttime awakening, a 30% decrease in albuterol use, and a 26% improvement in daytime symptoms. The oral compound MK-571 has also been found to improve asthma symptoms and pulmonary function and decrease beta-agonist use. Verlukast has shown similar effects, as have montelukast, pranlukast, and zileuton.

In general, the antileukotriene agents are very safe. Earlier agents that caused significant elevations of liver function tests are no longer manufactured, but some concerns regarding liver function remain. Zileuton ingestion has been associated with mild and transient elevation of liver enzymes that generally reverts to normal with continued therapy or cessation. The FDA has suggested that monitoring be done monthly for the first few months, and periodically thereafter. Churg-Strauss syndrome has been found in association with zafirlukast when corticosteroid anti-inflammatory therapy was being tapered. Thus asthma patients in whom corticosteroid therapy is being reduced should be carefully monitored. Adrenal suppression and cataracts have been mentioned as potential side effects; further study is required.

Antileukotrienes are currently recommended for mild persistent asthma by the National Heart, Lung and Blood Institute, and they may be effective in other subgroups of asthma.

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Combination Therapy for HIV Disease

As a result of recent advances, the treatment of HIV disease is now firmly based on HIV immunopathogenesis and viral dynamics. This paradigm shift—along with new, potent anti-retroviral drugs, a better understanding of drug resistance, and the ability to monitor viral load—has engendered updated recommendations for antiretroviral therapy.

The concept of virologic latency after primary HIV infection is no longer tenable. HIV immunopathogenesis reveals that viral replication and clearance, as well as CD4$^+$ cell destruction and replacement, are rapid, continuous, high-level processes at all stages of the disease. Estimates suggest that 10 billion virions and two billion CD4$^+$ cells are produced and destroyed each day, and that the plasma virus half-life is only six hours. More than 99% of plasma viremia results from these ongoing cycles of infection in CD4$^+$ lymphocytes. Eventually, the immune system is overwhelmed by the unrelenting assault.

HIV infects multiple cellular compartments. Actively productive CD4$^+$ cells with short half-lives make up the first compartment, the major reservoir of virus in the body. A second compartment of longer-lived tissue macrophages and follicular dendritic cells accounts for 1% of the viral burden. A third compartment of chronically infected cells may exist (perhaps in the brain and cerebral spinal fluid), offering proviral DNA a long-term, possibly lifelong, sanctuary site. The mathematical model for eradication of HIV suggests that complete viral suppression for a period of 2 to 3 years may eradicate the virus from the host in the first two compartments, but a risk of relapse remains from the sanctuary sites.

The ability to quantitate the level of HIV-1 RNA in the plasma (viral load) has been essential to our increased understanding of viral pathogenesis and antiretroviral efficacy. Viral load is a practical and reliable marker of disease progression and treatment benefit.

Recent data have demonstrated a strong relationship between viral load and clinical outcomes. Natural history studies have demonstrated that baseline viral loads predict over a 10-year period of observation the rate of CD4$^+$ T-lymphocyte decline, the time to AIDS, and the time to death from AIDS. Similarly, clinical trials of nucleoside reverse transcriptase inhibitors, nonnucleoside reverse transcriptase inhibitors, and protease inhibitors have consistently shown a strong correlation between reductions in viral load and reduced risk of CD4$^+$ T-cell decline, AIDS, or death from AIDS.

Within the past year, five new drugs have been approved for the treatment of HIV-1 infection: two nonnucleoside reverse transcriptase inhibitors (nevirapine and delavardine) and three protease inhibitors (ritonavir, indinavir, and nelfinavir). The addition of these agents has resulted in a growing number of potent virus-suppressing combination regimens. The term "highly active anti-retroviral therapy" (HAART) has been coined to describe these new, very effective, combinations.

The promise of these new combinations notwithstanding, it has become clear that the development of drug resistance remains the Achilles heel of anti-retroviral therapy. A new generation of HIV is produced in 2.6 days, yielding 140 generations per year. Assuming 10 billion replicative cycles per day, every possible mutation in the HIV genome can occur several times a day. Consequently, if HIV replication is not completely arrested, mutants will rapidly arise. Genotypic and phenotypic laboratory assays for drug resistance are in development.

Potent anti-retroviral combination regimens initiated in moderately advanced disease have demonstrated impressive immunologic, virologic, and clinical responses. The immunologic response is incomplete, however, with respect to full restoration of CD4$^+$ cell number and function, thus arguing in favor of earlier intervention.

The mantra of HIV therapy has become "hit early, hit hard." Significant scientific rationale exists for the new, more aggressive goal of suppressing HIV replication as completely as possible throughout the entire course of infection. Powerful, theoretical rationale exists as well for intervening as early as possible in the course of HIV disease to avoid irreversible immune deficits. Highly effective combination anti-retroviral therapy is the new standard of care.

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Advances in Allergic Rhinitis Pharmacotherapy

A recent survey shows the prevalence of allergic rhinitis to be at least 14% in the U.S. population. Therapeutic options for allergic rhinitis are threefold: pharmacotherapy, immunotherapy, and environmental control. Pharmacotherapy has provided the major advances over the last 10 years with regard to improved efficacy and safety in the treatment of this disease.

Five agents are now available in the category of oral second-generation antihistamines: terfenadine, astemizole, loratadine, cetirizine, and fexofenadine. These histamine receptor antagonists are less sedating than their first-generation predecessors, and thus are well tolerated by patients. Terfenadine and astemizole, however, can cause QT prolongation and, in rare cases, a serious and potentially fatal cardiac arrhythmia. The Food and Drug Administration has therefore recommended removal of terfenadine from the market. The other three agents do not appear to have this property. Advantages of the second-generation antihistamines include a complete lack of somnolence and mental impairment (astemizole, loratadine, fexofenadine), the convenience of once-a-day (astemizole, loratadine, cetirizine) or twice-a-day (terfenadine, fexofenadine) dosing, and, consequently, improved patient acceptance and compliance. Liquid preparations and pediatric indications (age six years and up) now exist for loratadine and cetirizine. Certain antihistamine-decongestant combination agents are on the market, although patients who use them need to be warned about potential stimulatory side effects from the decongestant. Second-generation antihistamines have also recently become available for topical use. Azelastine hydrochloride, a moderately effective intranasal spray, is particularly useful in decreasing nasal itching; mild sedation occasionally occurs due to its systemic absorption via the nasal mucosa.

The well-proven potency, efficacy, and safety of intranasal corticosteroids have made them the drugs of choice for any patient with frequent, chronic, or severe symptoms of allergic rhinitis. A number of topical agents are available (beclomethasone diproprionate, budesonide, flunisolide, fluticasone, triamcinolone, dexamethasone). Comparison studies evaluating topical steroids versus oral antihistamines repeatedly show intranasal corticosteroids to be superior. Unlike all other pharmacotherapy agents, when used alone, intranasal corticosteroids can improve all four of the major symptoms of allergic rhinitis (itch, rhinorrhea, sneeze, and congestion). Their use has increased for a variety of reasons, including a better understanding of the inflammatory nature of allergic rhinitis and the decision to introduce them earlier and maintain them longer when allergen exposure or symptoms continue. They are available as either a wet aqueous spray or a dry aerosol spray, making them convenient and well accepted by most patients. Differences in clinical efficacy between agents is minimal, so selection of a specific nasal steroid usually depends on cost, formulary availability, and patient preference (aqueous or aerosol). At recommended doses, intranasal corticosteroids are free of significant adverse effects.

Another topically active anti-inflammatory agent, cromolyn, has been found to be so safe after years of use that it was recently made available without a prescription. Cromolyn is an nonsteroidal nasal spray whose mode of action is primarily preventive via mast cell stabilization and, overall, less effective than nasal corticosteroids.

Oral anticholinergic therapy has been tried for years as therapy for allergic rhinitis, but adverse effects (such as dry mouth and eyes) have limited its use. A topical anticholinergic medication has recently become available that circumvents the side effects of the oral form ipratropium bromide. This nasal spray, available in two strengths (0.03 and 0.06%), appears to be an effective adjunct in controlling rhinorrhea.

New agents and approaches hold additional promise for the treatment of allergic rhinitis. The leukotriene receptor and pathway antagonists, available for asthma, are being tested as therapeutic agents in oral and topical forms. Monoclonal antibodies to IgE and to cytokines important in allergic inflammation are still in early experimental stages but will likely be tried as therapy for this disease.

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Treatment of Chronic Urticaria

CHRONIC urticaria is a disease of unknown origin. In a study of chronic urticaria patients, a five-day diet of rice, lamb, and water had no effect on the majority of symptoms; thus its manifestations were not due to an exogenous foodstuff or food additive. The theory that chronic urticaria is, rather, an autoimmune disorder holds in at least 40% of patients. These patients have an IgG antibody directed to the α subunit of the IgE receptor on cutaneous mast cells. Mast cell degranulation may lead to a late phase-like cutaneous reaction that causes the infiltrative hive characteristic of chronic urticaria. This infiltrate consists of a perivascular collection of $CD4^+$ T lymphocytes, a surprisingly large number of monocytes, perivascular mast cells, and variable numbers of eosinophils with eosinophil-derived cationic proteins identifiable in about 65% of subjects even if intact eosinophils are not evident.

In an additional 50% to 60% of patients, IgG anti-$Fc_{\epsilon}RI\alpha$ antibody is not demonstrable functionally (histamine release) or by binding (immunoblot directed to α). The cause of their condition remains an enigma. In addition, some patients' sera cause histamine release but do not bind to the α subunit, suggesting an alternative mast cell degranulating substance in their sera. It is curious, and so far unexplained, that these autoantibodies, when present, lead only to cutaneous disease rather than rhinitis or asthma.

The aforementioned observations support treatments other than high-dose antihistamines for treating chronic urticaria. For example, a gradually tapering alternate-day steroid protocol may be effective for severe disease. The rationale for steroid administration is no different from its rationale in allergic rhinitis or asthma, but in this case, systemic rather than topical administration is required. Experimental approaches to treating chronic urticaria include plasmapheresis and administration of intravenous gamma globulin or cyclosporine, but further studies are needed.

Steroids cannot directly inhibit cutaneous mast cell degranulation, emphasizing the importance of the cellular infiltrate in the pathogenesis of chronic urticaria. In contrast, most physically induced hives (cold urticaria or dermatographism, for example) are generally unresponsive to corticosteroids but respond to antihistamines because they have no associated late phase response and the symptoms are due solely to mast cell degranulation.

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Inhaled Corticosteroids for Asthma Therapy

INHALED corticosteroids, which suppress both the inflammatory process and the bronchial hyperreactivity that are characteristic of asthma, have become the first-line therapy for long-term control of chronic asthma. Because inhaled corticosteroids are delivered in very small doses directly to the airways, they cause far fewer side effects than larger doses of corticosteroids delivered systemically. Accordingly, there is a growing trend toward using these agents in even the mildest cases of asthma. In fact, a recent report demonstrated a decreased risk of hospitalization for asthma with the use of inhaled corticosteroids.

The inhaled corticosteroids currently available in the U.S. for treating asthma include beclomethasone dipropionate (BDP), budesonide (BUD), triamcinolone acetonide (TAA), flunisolide (FL), and fluticasone propionate (FP). Few comparative trials have examined the different products; there is a need for more studies.

The ideal inhaled corticosteroid should have low systemic bioavailability, high topical potency, and rapid clearance of the portion that reaches the systemic circulation. Only 10% to 15% of the inhaled dose of corticosteroid reaches the lungs, and the balance is deposited in the posterior pharynx and oral cavity or is ingested. The portion of the absorbed drug not neutralized by a first pass through the liver enters the systemic circulation. Safety is paramount because these drugs are used over a long period of time and frequently in children. While it is sometimes assumed that all inhaled corticosteroids have essentially equivalent efficacy, differences in safety profiles do exist.

BDP is the most widely studied inhaled corticosteroid. It has efficacy similar to a TAA dose, which delivers twice the micrograms per inhalation. BDP is metabolized to its active form in the lung. Its active metabolite has a greater affinity for corticosteroid receptors than BUD but is equivalent in its therapeutic efficacy and safety profiles. On the other hand, 1000 mg of BUD (in dry powder form) achieves lung deposition approximately twice that of 1000 mg delivered by metered dose inhaler (MDI), suggesting a greater bioavailability with the dry powder form. Systemic bioavailability of BUD and FP is determined principally by their bioavailability in the lung.

BDP and BMP have the shortest half-lives—30 and 37 minutes, respectively. The elimination half-life for BUD is estimated to be 2.3 hours, whereas the elimination half-life of FP is 7.8 hours, the longest of all the inhaled steroids. The systemic bioavailability of FP from the lungs is 30% of the drug delivered from the actuator. FP therefore produces a roughly three-fold increase in the likelihood of systemic side effects because of its prolonged half-life and greater absorption from the lungs.

The potential for systemic side effects, such as hypothalamic pituitary-adrenal axis suppression, cataracts, and growth retardation, rises with increasing doses of inhaled corticosteroids. Therefore, the need for high doses of inhaled corticosteroids in a patient should be constantly reassessed so as to administer the lowest effective dose. In one study, when the same microgram doses of BDP, TAA, and FL were administered, equivalent suppression of 24-hour urinary-free cortisol excretion was observed. FP had greater adrenal suppression than BUD, however, at equivalent microgram doses even when accompanied by a mouthwashing procedure to prevent oral bioavailability.

Overall, selected inhaled corticosteroids (such as BDP) have been associated with remarkably few side effects at doses up to 400 μg per day in children and up to 800 μg per day in adults. Even at higher doses—up to 2000 μg per day—relatively few adverse events have been reported. In conclusion, the small risk associated with inhaled corticosteroids must be balanced against the far greater dangers of failing to control chronic asthma.

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Intravenous Immune Globulin in Neuromuscular Disorders

INTRAVENOUS immune globulin (IVIG) is a polyvalent immunoglobulin that contains more than 90% monomeric IgG with small amounts of other immunoglobulins, such as IgA, IgM, and possibly IgE. It is prepared from plasma derived from a large pool of volunteer donors. (The donors are well screened for human immunodeficiency virus [HIV], human T-cell lymphotropic virus, and the hepatitis A, B, and C viruses. In addition, HIV and hepatitis B virus are inactivated by a fractionation process, and the plasma is treated with solvents, detergents, or enzymes and incubated at low pH to inactivate hepatitis C and other viruses.)

IVIG is primarily used as a replacement therapy for patients with antibody deficiencies. The successful use of high doses of IVIG to treat children with idiopathic thrombocytopenic purpura led to high doses (approximately a total initial dose of 2 g/kg body weight over five consecutive days) being used in a large number of autoimmune disorders, including several neuromuscular disorders. In some, such as Guillain-Barrë syndrome, chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, and dermatomyositis, the results of controlled clinical trials have demonstrated definite beneficial effects. In fact, a number of controlled studies, including multinational and multicenter studies, of Guillain-Barrë syndrome—a monophasic acute demyelinating polyneuropathy characterized by severe weakness or paralysis of limbs and respiratory muscles—have demonstrated that high-dose IVIG therapy is at least as effective as plasmapheresis or combination of IVIG and plasmapheresis. The efficacy of IVIG in other disorders is either anecdotal or not fully substantiated by controlled studies. The beneficial effect of the combination of intravenous methylprednisone plus IVIG over IVIG alone remains to be determined.

Taking into consideration cost, safety, convenience, and practicality, IVIG is preferred for small children or patients with poor venous access, patients with severe autonomic dysfunction or compromised hemodynamics, and patients in hospitals in which plasmapheresis is either not available or not routinely performed.

Unlike Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy (CIDP), characterized by the slow onset of weakness, areflexia, and impaired sensation, requires long-term therapy to maintain improvement. The treatments for CIDP are steroids, high-dose IVIG, and plasmapheresis. The response to steroids is sometimes slow, and prolonged therapy increases the risk for severe side effects. Controlled and randomized studies have demonstrated that high-dose IVIG and plasmapheresis are equally effective in improving muscle strength, neuropathic symptoms, and amplitude of evoked muscle-action potentials. At this stage, it is unclear what dose should be used for maintenance therapy, although a monthly administration of 1 g/kg body weight has been recommended.

Multifocal motor neuropathy (MFMN) is a disorder of slow onset of weakness and muscular atrophy with areflexia and without sensory loss. It is characterized by conduction block of the motor axons and by the presence of GM1 ganglioside antibodies. IVIG is the treatment of choice for MFMN. IVIG therapy is associated with diminution of symptoms and resolution of electrophysiological conduction block, although GM1 antibody titers may be unaffected. If the efficacy of IVIG therapy diminishes after several months of treatment, the coadministration of intravenous cyclophosphamide may be indicated.

Dermatomyositis is a myopathy characterized by weakness of proximal muscles, violaceous rash on the face and extremities, and deposits of immune complexes in the capillaries. Double-blind and controlled studies have demonstrated that high-dose IVIG induces clinical improvement that is associated with inhibition of the deposition of components of complement activation and downregulation of intercellular adhesion molecule-1 and major histocompatibility complex (MHC) class I. Since steroids are the treatment of choice, IVIG is indicated for steroid-resistant patients or for patients in whom steroids are contraindicated.

The side effects of IVIG treatment occur in less than 10% of cases, and are usually minor: mild-to-moderate headache, chills, myalgia, chest discomfort, fever, fatigue, and nausea. Most of the side effects can be prevented or treated by administration of nonsteroidal anti-inflammatory agents and by slowing the rate of IVIG infusion. Aseptic meningitis occurs in 10% of cases, responds to strong analgesia, and subsides in 24 to 48 hours. Other rare adverse reactions include skin rash, anaphylaxis, and renal tubular necrosis.

The mechanisms by which IVIG exerts its beneficial effects in neuromuscular disorders are not clearly understood, but various immunomodulatory effects have been proposed. IVIG contains a variety of anti-idiotypic antibodies that bind to and neutralize pathogenic autoantibodies, thus preventing their interaction with self-antigens. Along with IgG, molecules in IVIG that have immunomodulatory effects in neuromuscular disorders include antibodies to various cytokines and T-cell receptors and soluble CD4, CD8, and MHC class II antigens.

Determination of the optimal dose, frequency, duration, and the mechanisms of action of IVIG in various neuromuscular disorders will continue to challenge scientists. Meanwhile, because IVIG is expensive, the clinician should be judicious in the use of MHC as a therapeutic agent in neuromuscular disorders.

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Screening of applications will begin 11 may 1998. Applications and nominations will be accepted until the position is filled. The scope and responsibilities of this position require a complete review of credentials and background. Finalists will be asked to sign relevant releases.

Iowa State University is an equal opportunity/affirmative action employer and encourages nominations of, and applications from, women and minority candidates.

Commentary

The Need for Single-payer Catastrophic Health Insurance

Abstract.—Both physicians and patients are becoming increasingly frustrated with the decreasing flexibility of our health-care system. Forty-one million citizens remain uninsured while ill patients in managed-care plans find themselves subject to bureaucratic hurdles in attempting to obtain necessary care. Rather than relying on the market place to provide affordable insurance to patients, physicians should embrace single-payer catastrophic coverage. A government insurance program should be enacted that covers all medical bills that exceed a $15,000 deductible annually for families and a $10,000 deductible annually for individuals. Patients could then purchase plans through the private sector to cover these deductibles. While such a plan would require a tax increase, premiums would decrease, health insurance would become more affordable to low wage earners, and more treatment decisions would be made by physicians and patients.

Practicing medicine has become a frustrating vocation. While physicians continue to learn new therapies and advanced surgical techniques to improve the lives of their patients, a constant drumbeat by both the government and the private sector to control costs is turning medicine from the art of healing to the art of battling byzantine bureaucracies. Meanwhile, more and more patients are falling through the cracks—even in supposedly good economic times—as health insurance costs escalate. Forty-one million Americans, 17.6% of the under 65 population, are uninsured, the highest in recent history.[1]

The primary response of the medical community to this disturbing trend has been either to fight the bureaucratic excesses of managed care or to attempt to organize health insurance plans controlled exclusively by physicians. Neither of these approaches will address the underlying reason for the unaffordability of health insurance: the wages of workers have not kept pace with the escalation in health-care costs.

As can be seen (Fig. 1) per capita health-care costs have increased 23-fold since 1970 while wages have increased only 4-fold. The problem is further compounded by increasing disparities of wealth. Over the past 25 years, the poorest 5% of the population have seen their inflation-adjusted wages plummet 34% while the wealthiest 5% have realized a 43% increase.[2] Low-income families (less than $12,841 annually) spend 9.4% of their income on health care, whereas high-income families (greater that $96,122 annually) spend 1.2%.[3] It is not unusual for a working-poor family to earn $12,000 annually but be expected to come up with $4,000 for health insurance—33% of their income. It is small wonder that so many are uninsured.

Rather than battle managed-care conglomerates, the medical community should ally itself with their patients to establish a more equitable way for financing health care by endorsing single-payer catastrophic coverage for all Americans.

Historical Perspective

For most of the country's history, health care has been a private contract between the doctor and patient, with Adam Smith looking over the shoulders of both. But during the first half of the 20th century, medical advances changed public perception. The advent of antibiotics and advancing surgical techniques made the public realize that doctors could also cure them, not just comfort them. In 1900 the life expectancy in the United States was about 45 years, and the biggest killers were tuberculosis, pneumonia, and diarrheal diseases. By 1950, life expectancy had increased to 65 years and these three diseases were coming under control.

After World War II, health insurance was offered as a benefit of employment, allowing a significant percentage of the population to have unfettered access to physicians. This resulted in a disparity of care. The retired elderly and the poor were unable to obtain affordable health insurance. This was remedied in the 1960s by legislation that established Medicare for the population over 65 and Medicaid for the poor.

Concurrently, technological advances in medicine were moving exponentially, and there was a 38-fold increase in health-care spending between 1960 and 1996. Selective

Figure 1

Year	Average Annual Wage	Average Annual Health Cost	% of Wages
1970	$8,734	$159	1.8%
1980	17,710	752	4.2%
1985	23,618	1,551	6.6%
1990	29,943	2,771	9.2%
1995	34,076	3,759	11.0%

Adapted from Health Care Financing Review, 1997 Statistical Supplement, p 20. And Wages. *The New Republic*. September 1996:16.

anti-biotics, antihypertensives, tranquilizers, cardiac bypass surgery, cataract surgery, joint replacement along with diagnostic tests such as computed tomographic scans, angiograms, and magnetic resonance imaging resulted in increasing physician specialization and the need for highly-trained support staff. Price escalation was a natural consequence. Insurance companies, employers, and the government began to question the blank check that the medical community had previously enjoyed. Medicine had become a victim of its own success.

The Failure of Managed Care

Scattered examples of managed care have been around for decades, the most successful being a plan started by the Kaiser Foundation in 1945. For a fixed price, patients were offered comprehensive care but had to use doctors employed by Kaiser and abide by their decisions. While several imitations of the Kaiser system were developed, it was not until the 1980s that health maintenance organizations became popular. In general, these consisted of panels of physicians who agreed to care for patients at set fees. To control costs, physicians agreed that the insurers had the right to preapprove certain procedures and to control specialist referrals, hospital admissions, and access to emergency rooms—managed care.

The underlying theory of managed care was that both physicians and patients were overutilizing the health-care system. By decreasing prolonged hospital stays, unnecessary office visits, and unnecessary surgery, health-care costs could be contained.

The system seemed to work, at least ostensibly. In 1986, health-care costs increased by 8% over the previous year even after correcting for inflation, but by 1996, the rate of increase was a mere 1.9%.[4] These savings gave most patients little choice but to join managed-care plans, with many employers not offering them other options. Forty-nine percent of firms with less that 200 employees offered their workers only one health insurance plan.[5] By 1997, 80% of workers were in managed-care plans.[6]

While physicians voiced anecdotal complaints of patient abuse, these fell on deaf ears. But as time passed, patients began to complain too. Mothers bringing their crying infants to the emergency room were denied approval for payment unless a serious problem was noted. The mother of a crying infant who was teething may have been presented with a bill for hundreds of dollars. Patients who presented to emergency rooms with chest pain that was found to be heart burn met a similar fate.

Meanwhile, managed care became draconian in denying prolonged hospital stays for childbirth and surgical procedures. For example, some companies mandated that a woman undergoing cesarean section had to be discharged within 48 hours. Yet, through the use of legal legerdemain, the obstetrician remained liable for any complications to both mother and child even though faceless managed-care bureaucrats were calling the shots.

The insurance companies have had the ability to exclude patients with pre-existing conditions. In 1996, federal legislation, the Kassebaum-Kennedy law, attempted to end this practice. But vague regulations and lax enforcement of the law have enabled the insurers to raise premiums on sick patients to unaffordable levels, in some cases eclipsing $10,000 annually.[7] As stated by Mr. James Tallon, President of United Hospital Group, "The best way to make a buck in insurance is to sell it to healthy people."[8]

Patients were further lured by gimmicks such as $2 copays for doctor visits along with free eyeglasses, hearing aids, and prescriptions. Once captured, copayments were rapidly increased and benefits were quickly reduced. Patients with pre-existing conditions were stuck.

To control costs, managed care initiated various policies. The concept of capitation was devised, whereby physicians were paid a fixed amount per patient whether care was provided or not. Primary-care physicians were given the title of "gatekeeper" and paid bonuses for not referring patients to specialists. Academic centers, the training ground for future physicians, were forced to care for patients for less than their overhead. Some companies went further, instituting "gag rules" that specifically prohibited physicians from telling patients of uncovered treatment options!

Meanwhile, the true nature of managed care was revealed as executives began taking payolas that would embarrass Croesus. Leonard Abrahamson sold the company he founded, U.S. Health Care, to AETNA for stock valued at over $1,000,000,000 (your eyes are fine, that is a one with nine zeros after it).[9] Former Oxford Health Plans CEO, Steven Wiggins sold a large number of his shares worth millions several weeks before the stock crashed 62% in a single day.[10]

It became obvious that the name of the game in managed care was to sign up enrollees, show high short-term profits to Wall Street, and inflate the price of the stock. Once this occurred, the managed-care executives exercised lucrative options or sold out and walked away with millions. Oxford, with its stock now languishing at a sixth of its previous value, is threatening to increase the cost of individual policies by 69%, and huge premium increases are occurring in managed-care plans all over the country.[11]

The failure of managed care is due to an incorrect underlying assumption: by wringing out waste and abuse in the health-care system, costs can be controlled. In actuality, it is advancing technology and the increasing ability of the medical profession to solve what were previously untreatable medical problems that has caused costs to increase. In fact Professor John Newhouse of Harvard's Kennedy School of Government estimates that over 50% of health-care cost escalation is due to advancing technology.[12]

Taking care of sick people costs money—lots of money. The only way to cut costs is to deny care. Yet, managed care continues to march forward. The reason: the medical community has not yet offered a viable alternative.

Single-payer Catastrophic Coverage

Single=payer catastrophic coverage would insure all Americans for medical bills that exceed a certain annual amount. For the sake of this discussion, the number $10,000 was chosen for individuals and $15,000 for families. While an entirely new government program could be proposed to administer this plan, it would seem more logical to extend Medicare, which is financed by a 2.9% payroll tax, to all Americans. Care must be taken to simplify Medicare's coding system.

Treatments should be placed into three categories (Fig. 2). The first category would consist of known effective treatments such as appendectomies and medications for hypertension. This category would be covered 100%. The second category would consist of treatments deemed experimental or those of uncertain benefit such as bone marrow transplants in some types of cancers. Coverage would be between 50% and 75%. Patients could buy supplementary insurance for such treatments. A third category would consist of noncovered items such as cosmetic surgery.

Because such a classification system would be fluid based on new developments, a committee of physicians including epidemiologists would oversee the program.

Single-payer Catastrophic Coverage (examples)

1. Class 1.—Treatable Illnesses (100% coverage). All emergency care, diabetes, broken limbs, heart attacks, breast cancer, obstetric care, asthma, hypertension vaccinations, hospice care for the dying.
2. Class 2.—Illnesses where treatment may help (partial coverage). Metastatic lung cancer, back pain.
3. Class 3.—Cosmetic procedures (no coverage)—Face lifts, laser procedures to eliminate glasses.

Economic Analysis

Predicting the cost of such a program is a formidable task as it requires projections on population growth, medical advances, and changing human behavior patterns. In 1996, health-care costs passed $1 trillion dollars for the first time. Of this amount, $481.3 billion was financed from the public sector (eg, Medicare and Medicaid) and $552 billion from private funds (eg, private insurance and out-of-pocket expenses). Thus it can be seen that already, almost 50% of health-care cost is financed by the taxpayers. Raising the Medicare tax from 2.9% to 4.1% would bring approximately $80 billion.[4(p.41)] While more research is needed for conformation, this should be adequate in protecting all Americans for catastrophic medical expenses who are not already covered by Medicare and Medicaid.

The benefits would be immediate. Many patients, no longer faced with the specter of bankruptcy, would be empowered to choose polices that meet their needs rather than meekly accepting the mandates from their employers and the insurance companies. Those with pre-existing conditions would not run the risk of financial ruin by attempting to obtain improved coverage. Companies would no longer be in a position to make patients jump through hoops to see a specialist or go to the emergency room. Ethical insurance companies could concentrate on producing a quality product rather than trying to figure out how to exclude sick patients.

The market place would determine how patients cover this large deductible. Most patients would opt to purchase insurance. Some patients may prefer medical savings accounts. Some will decide to go without insurance but public policy makers could consider requiring employers to give low-wage workers health benefits.

Large savings would materialize in that hospitals would not need so many administrators to battle with the different companies. Most important, the doctor-patient relationship would improve, as physicians no longer have to grovel for permission to take care of their patients. The use of capitation, gatekeepers, and gag rules would diminish.

Discussion

It will be argued that the introduction of single-payer catastrophic coverage is the first step towards socialized medicine and the demise of the most advanced health-care system on the planet. After all, other countries who developed socialized systems have found themselves without capital investment from the private sector, leaving their hospitals as large wards.[13] It is no surprise that the majority of medical developments—small-incision cataract surgery, small-incision abdominal surgery, drugs to slow the progression of AIDS—were spawned in the United States.

What must be realized is that the United States already has a hodgepodge of programs to protect its citizens from financial ruin. Medicare protects the senior citizens (65 and older) and the disabled. Medicaid protects the unemployed poor. For the uninsured, there is a patchwork of programs available. In New York City, 11 public hospitals serve the uninsured. In Connecticut, a 17% tax is placed on the hospital bills of the insured to cover the hospitalized uninsured.

During its last session, the most conservative Congress since World War II authorized programs to insure the children of the working poor. In this year's State of the Union address, President Clinton proposed that those over 55 be allowed to buy into Medicare. These developments reflect the overwhelming majority view of the American people that the government should protect its citizens from large health-care bills.

Those who oppose single-payer catastrophic health insurance must ask themselves: What is the alternative? Some may wish to return to the previous fee-for-service arrangement. This is not going to happen. The insurance companies will not allow it and individuals cannot afford it.

Others may feel that physician-run managed-care companies are the wave of the future. Yet, past history demonstrates that physicians who are successful in establishing such companies quickly trade in their stethoscopes for pre-Castro Cohibas. Columbia CEO Thomas F. Frist exercised stock options that netted him $125,000,000.[14] When Norman Payson, the CEO of New Hampshire's Health Source Inc., cashed in his chips, he walked away with $90,000,000.[15] Both Frist and Payson are physicians.

Some are of the opinion that physicians need to unionize. But it unlikely that steelworkers and coal miners will be willing to march hand-in-hand with physicians whose annual incomes average $189,000.[6] Others feel that with effective lobbying, antitrust provisions can be repealed; thus, improving the bargaining position of the medical community when dealing with the insurance companies. Presently, physicians who discuss fees with other physicians are committing a felony and are subject to fines of $350,000 and three years of jail.[16] Even in the unlikely scenario that physicians could muster the political clout to change this, court challenges would tie up the issue for years if not decades. Furthermore, such action would not make health insurance more affordable for the average citizen.

It may be argued that physicians should continue to muddle through the managed-care trend and hope that it eventually ends. This is hopelessly naïve. Managed care is just scratching the surface of cost-cutting measures. Through the use of genetic screening and sophisticated data bases, insurance companies will even further perfect the art of insuring the healthy. They will establish networks of paraprofessionals, physicians assistants, nurse practitioners, naturopaths, and chiropractors who are willing to work for a fraction of the salaries physicians now enjoy. Physicians who believe that the public will never accept such an arrangement must ask themselves: How many patients remained in your practice when you were no longer covered by their insurance? The only health-care change that the public will not tolerate is one that results in large out-of-pocket expenses.

Physicians have a choice: they can either be cannibalized by insurance conglomerates who have mastered the art of caring for the healthy and punting the sick to the taxpayers while making obscene profits, or they can support a system that evenly distributes the risk of caring for the unfortunates with illnesses.

Summary

Physicians must unite and fight for a plan that makes insurance affordable while preserving the market forces that have made health care in the United States the envy of the world. Single-payer catastrophic coverage is a reasonable alternative to the patchwork of private and public health care plans that attempt to prevent patients from falling through the cracks. Furthermore, by proposing such a plan, physicians will be seen by their patients as their advocates, rather than just another special interest group trying to preserve its income.

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Joseph F. Bentivegna, M.D
Rocky Hill

50 Years Ago

From *The Connecticut State Medical Journal*

April 1948

The Hartford Hospital Medical Center

ON Sunday afternoon, March 14, the new $8,000,000 building of the Hartford Hospital was dedicated. The ground was broken for this new building 9 days after V-J day and, in spite of shortages of materials and labor problems, construction has continued apace until now it is completed and ready to receive patients. This building is 14 stories high and features many step-saving devices which it hoped will aid in offsetting the manpower shortages, especially those in the nursing departments. These devices include two vertical conveyor systems installed for the first time in a hospital building. Goods and articles are put in large fibre baskets and carried from floor to floor. Over four miles of pneumatic tubing goes to every department to make possible the sending of medical records and material. A call system operates between every patient's bed and nurse's station and between the station and the kitchen, service room, etc.

The hospital in the new building will have 978 beds, a total of 122 more adult beds than in the old building This includes the maternity beds and 168 bassinets in the South Building which was erected in 1941-1942. It does not include Avery Convalescent Hospital. One of the new features is the neuropsychiatric floor with 90 beds and an isolation floor with 9 beds, both designed to care for cases coming within these categories and developing among patients already within the hospital. The largest rooms in the new hospital will contain but 4 beds and nearly all floor units will have 27 beds. The hospital also has an amphitheatre seating 151 persons, to be used for teaching purposes. Balconies in 4 of the 16 operating rooms and in the local anesthesia room will enable students and visiting physicians to observe without entering the rooms.

Wilmar M. Allen, M.D., director of the Hartford Hospital, gave the dedication address to a gathering of about 500 friends. Mr. William H. Putnam, president of the hospital, was master of ceremonies. Those taking part in the presentation and acceptance of the key were David P. Appell, vice-president of the George A. Fuller Co., contractors; Henry R. Shepley of Coolidge, Shepley, Bulfinch and Abbott, architects; Norman B. Bertolette, chairman of the building committee; and H. Gildersleeve Jarvis, M.D.,

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Reprinted from the *Connecticut State Medical Journal*, March 1948.

chairman of the building committee of the staff. The Reverend Sidney W. Wallace, Canon of Christ Church Cathedral, pronounced the benediction.

Just 10 days prior to the dedication of the new Hartford Hospital building, ground was broken for a new 8-story structure designed to accommodate 90 physicians' offices. This new office building will adjoin the new hospital on the north and will cost about $1,500,000 to construct. It will be erected by the Connecticut Mutual Life Insurance Company on property sold to the insurance firm by the hospital.

The first floor of the new office building will contain several shops, including a pharmacist, a florist, and a barber, and such other shops as may be deemed advisable for the convenience of tenants, patients and visitors. An L'shaped plan has been evolved by the architects, Moore and Salisbury, providing elevators and services at the center and corridors running at right angles to each other.

The main entrance will be protected by a marquee faced with stainless steel, and the first level will have a continuous hood over display windows and stone piers. The materials to be used for the new building will be in harmony with those used in the hospital building. The walls will be of white "vitrigranite" brick.

The building will be equipped with a system of forced ventilation, introducing fresh air into the main corridor on each floor, and all interior rooms and spaces will be mechanically exhausted by ducts through the roof. Heating will be provided through inconspicuous flush copper convectors, concealed under windows and supplied by a zoned system from steam piped from the hospital's power plant. Gas will be available in the corridor ceiling of each floor, and light and power outlets will be located to suit tenants.

All interior columns will serve as pipe and vent shafts, making it possible to install plumbing fixtures wherever necessary. Sound control, as well as accessibility of pipes and conduits, will be afforded by a demountable perforated metal pan and mineral wool ceiling throughout.

The Medical Building will contain a laboratory managed as a private enterprise but which will be closely affiliated with the hospital pathological department.

By its close proximity to the hospital this new medical building should mean the saving of considerable time to the 90 members of the staff who will rent the new offices. The committee of the staff who planned this project with the insurance company comprised Thacher W. Worthen, chairman; Charles S. Mirabile, secretary; Philip J. McLellan, Louis F. Middlebrook, and Benjamin V. White. The 8-story building will be directly connected with the new hospital through the first 4 floors. Construction is anticipated to require about 1 year for completion.

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Engaged in the Dialogue

This past month the American Medical Association hosted its annual leadership conference in Washington, D.C. Invited to participate, in addition to interested members, were the officers and executives representing the various organizations comprising the Federation of Medicine.

The conference afforded an unique forum for the dissemination of information, the collation of ideas and an opportunity to examine from various perspectives the challenges confronting all of us at this stage in our history.

There is, as I do not need to remind you, much to engage our attention because changes to our practices occur with a certain relentless inevitability.

Our own demographics are changing. Womean will comprise 50% of physicians in the next generation. One-third of young physicians when questioned do not believe that in the future they will possess clinical autonomy in their practice of medicine. Eighty-eight percent of physicians are involved in at least one managed-care contract. Thirty-three percent accept at least one capitated contract. Greater than 50% of us are contracted in Medicare and/or Medicaid managed care. One out of five of us are engaged in a direct contracting situation. These statistics generally are skewed West to East, but the trends are still generally upward. One out of eight surveyed physicians has had participation denied in at least one group contract.

If you can bear a little more statistical information, 75% of employed persons are enrolled in some form of managed care coverage, be it HMO, PPO, or POS. Thirty-three percent of the Medicaid population and 10% of the Medicare population are enrolled in these types of plans.

That said of us and of our patients, what of the employers? It is obviously true that the overwhelming driving force in this rush to managed care was the expectation of reduced costs in providing that coverage to their employees by the business community. While costs to the business sector have undoubtedly slowed, adjusted inflation figures for medical care in the United States have fallen from 16% in the 1960s and early 1970s, to the 4% to 6% range today, the solution to the cost dilemma is not at hand.

Cost concerns are legitimate and demand attention. Allowing our system to evolve to the point where the consumer is insulated from the cost of medical care by third-party payors has proven to be a recipe for disaster. Overpromised and underfunded medical care is caught between expectations of our own, our patients, and the system providers.

One result has been a rather precipitous decrease in the percentage of workers covered by employer-funded medical insurance packages. In California the percentage of workers covered under employer-sponsored plans has fallen from approximately 70% to 58%. Remember that by most accounts physicians' costs comprise less than 20% of the healthcare dollar in the first place. So attacking that segment of cost is doomed to have limited effect when discussing the global costs of health care. A past president of the AMA quotes a colleague in summing up this fraction of the equation thus: "Employees have become commodities to be auctioned off to the lowest bidder."

Business is increasingly interested in defined contribution plans, and in some areas, as I have written previously, in direct contracting.

There is an opportunity here for us if we are to regain and retain control of the delivery of medical care to our patient constituency. To control utilization and clearly articulate outcome data is the heart and soul of the issue. It is obvious, at least to me, that current systems of network integration are inadequate. Information systems and access to capital are critical to achieving our goals. An adequately capitalized physician organization must be more competitive than any entity having to disperse funds to shareholders.

Let us consider that ultimately our goal should be a system of expanded choices of financing mechanisms. Allow the individual ownership of insurance policies with the periodic right to change coverage. Allow employers to make defined contributions to the employees' plan choice. Redefine the existing tax credit system affecting this type of insurance.

continued on next page

Our market-based system should be strengthened to avoid a government-based system of price controls: limiting choice, stifling innovation, and leading to an overall decline in quality. Only physicians can manage care. Organizational structure is vitally important. We must have organizations of size both in numbers and capitalization in order to impact and control cost and quality of care.

In Washington the speakers roster was impressive. Included were General Colin Powell and Justice of the Supreme Court Antonin Scalia, the President of the United States, Senator Phillip Gramm, Senator Edward Kennedy, Speaker of the House Newt Gingrich, Congressman William Thomas, Chairman of the Health Sub-committee of the House Ways and Means Committee, and Nancy-Ann Minn DeParle, Administrator of HCFA.

They all conveyed a message of conciliation and non-confrontation. Expressed loudly and clearly was their willingness to engage us in a health-care dialogue. In no sense were we lectured to, but in every sense were we invited to participate in identifying and helping to resolve the meaningful issues challenging medicine as we enter the 21st century.

Stanley J. Keating, Jr., M.D.
President

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Tragic Fall or Angle of Repose?

ROBERT U. MASSEY, M.D.

> A rift in the clouds in a gray day threw a shaft of sunlight upon her coffin as her nervous, energetic little body sank to its last sleep. But the soul of her, the glowing, gorgeous, fervent soul of her, surely was flaming in eager joy upon some other dawn.
>
> *William Allen White*

WILLIAM Allen White was editor of the Emporia *Gazette*, a most admirable newspaper back in the early decades of this century. He wrote a tribute to his daughter, Mary White, a high school student whose funeral had been just the day before, and the quotation above was its final paragraph. Mary, an excellent rider, had been knocked off her horse by a low-hanging limb as she looked back to wave to a friend. She had just been accepted to enter Wellesley the next year, 1922.

We read White's essay in high-school American Lit back in 1937. I have read it several times since. We read many essays, poems, short stories, and novels in that class and in English Literature the next semester. Most of them have remained more or less in memory, and, I believe, have made a difference. A surprising number had to do with death—but not the violent, gory, obscene, and diabolical deaths with their criminal or sexual overtones that we permit our entertainers to spew upon our children in these enlightened *fin-de-siècle* years.

Deaths of young men and women, deaths of children, are deeply tragic. Samuel Johnson called every death violent " which is not gradually brought on by the miseries of age, or when life is extinguished for any other reason than that it is burned out. He that dies before sixty, of a cold or consumption, dies, in reality, by a violent death."

During my public school years in the 1920s and '30s, I recall four deaths among my contemporaries: three died before the age of 10, two from meningitis, one an accident; the fourth, a 16-year-old classmate died suddenly from a cerebral hemorrhage. Five adult members of my family died in those same years, two aunts, my grandfather, and two great-grandparents. I believe this was in no way unusual. Today the first three deaths, ages 33, 51, and 64, could undoubtedly have been prevented. My great-grandparents were "burned out," both in their 10th decade, ready to go.

Last month, George Will, one of my favorite columnists, wrote of his father's death at age 89. Even some of my more liberally-minded friends and relations, rarely given even to mentioning George Will except in anger, admitted that it was a first-rate essay. He quoted a line, "... when the 'summons comes to join the innumerable caravan.'" American Lit came to mind and I recognized, from some 60-year-old storage place, William Cullen Bryant's *Thanatopsis*:

> So live, that when thy summons comes
> to join
> The innumerable caravan which
> moves
> To that mysterious realm,...

Will had written of his father's death that "He was, it is safe to say, not sorry when the Dark Angel tapped him on his shoulder and said it was time to go."

> In earlier ages, much was made of the *ars moriendi* , the art of dying, of having "a good death." Nowadays, science often overwhelms that art. When death approaches the elderly on measured tread, they are apt to become tangled in the toils of modern medicine. Then the dying are pushed to the side of the stage as medicine becomes the leading actor.... medicine becomes problematic when it resists not the body's afflictions but the body itself.

In high-school English Literature among the many required memorizations were, of course, Hamlet's "To be, or not to be," and Browning's "Prospice,"('Fear death?—to feel the fog in my throat, The mist in my face, When the snows begin, and the blasts denote I am nearing the place, ...). Another was Kipling's "L'Envoi":

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

When Earth's last picture is painted, and the tubes are
twisted and dried,
When the oldest colors have faded, and the youngest
critic has died,
We shall rest, and faith, we shall need it—lie down for an
eon or two,
Till the Master of All Good Workmen shall set us to work
anew!

How delightfully late Victorian that now seems. But when I first read his poem, Kipling had been dead only one year! My father's favorite lines, which we also had to memorize, were from Tennyson's "Crossing the Bar," always placed at the end of any edition of the Laureate's poetry.

Sunset and evening star,
And one clear call for me!
And may there be no moaning of the bar,
When I put out to sea,

But such a tide as moving seems asleep,
Too full for sound and foam,
When that which drew from out the boundless deep
Turns again home.

Twilight and evening bell,
And after that the dark!
And may there be no sadness of farewell,
When I embark;

For though from out our bourne of Time and Place
The flood may bear me far,
I hope to see my Pilot face to face
When I have crossed the bar.

Will tells us that his father's favorite modern novel was Wallace Stegner's *Angle of Repose*. It is one of mine also. Angle of repose is a mining engineering term for "the angle at which sliding dirt and debris come to rest." It is a perfect metaphor, as Stegner and Will both point out, for the point in our decline at which we come finally and mercifully to rest, our angle of repose. Of his father he wrote, "Fred left life as he lived it, nobly composed, having reached his angle of repose."

My antique generation learned from poetry and narrative, which is the best way, to come to accept death as part of living, although we never used that kind of psychobabble. We never considered death to be unusual or an option, or that heroics were called for to stave it off when the jig was up. Cemeteries were all over the place, and we visited the graves of our dead friends and relatives from time to time on sunny Sunday afternoons, and almost always on Memorial Day, just to say hello and that we still remembered, and, perhaps unspoken, perhaps not, "We'll be seeing you one of these days!"

Our medical schools have recently rediscovered death, and, like the rest of us, have begun to listen to the complaints from those who depend upon us that physicians, or most of us, don't know beans about death and dying, that too often we walk away, or do things to and for our patients that are quite inappropriate. Sherwin Nuland says that we have allowed ourselves to become "besotted" with our science and technology. That may be. We do have a moral obligation to understand and know how to apply this amazing science and technology; we also have an obligation to know when to withhold it. William Osler knew that, in part because he had little science and technology to withhold. He wrote of the dying he had observed: "The great majority gave no signs one way or another; like birth, their death was a sleeping and a forgetting."

This Month's Reading in Review

TIMOTHY B. NORBECK

"People want to have access to physicians with whom they historically have a relationship. They don't see health care as a three-party relationship between the doctor, patient, and insurance company. They see it as a two-party relationship between the doctor and patient."

Jim Maloney, Connecticut U.S. Congressman
(5th District) and a member of the Congressional
Task Force on Health Care Quality.
The Republican American (1 February 1998)

Based on findings from a survey sample, the Pew Research Center Found that 35% of Americans "strongly favor" efforts to enact a patient's bill of rights for people in managed care plans.... Another 43% said they "favor" it, while only 13% said they "oppose" or "strongly oppose" it.... About 9% had no opinion.

Pew Research Center Release (10 March 1998)

Ninety-five percent of Texas Democrats voting in the 10 March Texas primary approved of a resolution calling on the party to push for legislation allowing physician choice for persons enrolled in managed-care plans.... With 99% of the vote tallied, 636,925 Democratic primary voters cast their ballots in favor of Proposition 1, with only 27,765, or 4.2%, opposing it.

San Antonio Express-News (11 March 1998)

Would you believe? Because of the value of his time at the office, were Bill Gates to see a $100 bill lying on the sidewalk on his way to work, he would actually lose money spending the few seconds required to stop and pick it up.

An item first published in *The Wall Street Journal*
and which reappeared in *Reader's Digest*
(March 1998)

Saying that the managed-care "system is chaotic and often inconvenient," *Newsweek* columnist Robert Samuelson argues that some regulation of health plans is necessary.... It was Alain Enthoven, "one of the godfathers of managed care," who said, 'Managed care could not exist without regulation. There have to be rules to sustain public confidence.'"

Newsweek (9 March 1998)

Every Police Officer's Dream: A plaintiff's police brutality lawsuit went to trial in New Haven this past December, and the West Haven police officer defendant was on the witness stand, claiming that the plaintiff had provoked the encounter by swinging a fist at the officer.... The plaintiff's attorney, skeptical of the testimony, asked the defendant police officer to demonstrate to the jury how hard his client, the plaintiff, had swung at him.... Before the lawyer could clarify what he meant by "demonstrate," the officer punched the lawyer on the chin, staggering him and forcing an immediate recess.

Chuck Shepard (18 February 1998)

"The lawyers for Big Tobacco are just guys who can't say no, especially when large fees are at stake. When Thomas á Becket said no to King Henry II's request that he lawyer a state takeover of the church, the king had him murdered. When Thomas More refused to renounce his Catholic faith, declare the king to be head of the Church in England, and legally rationalize the sovereign's divorce, King Henry VIII had him beheaded. Maybe that's why in our age attorneys Thomas á Becket and Thomas More are remembered as saints, not as lawyers."

Joseph A. Califano, Jr.
in *Forbes* (23 March 1998)

Only in America: "Martha A. Cherry: You are hereby notified that you will be removed from the Postal Service effective the close of business August 15. You are charged with 'Unsatisfactory Performance Resulting in the Expansion of Street Time.' On June 9, you were accompanied on your street delivery duties by your supervisor. It was observed that on your route you took small steps that could be best described as 'baby steps.' You walked at a rate of 66 paces per minute with a stride of less than one foot. At each step, the heel of your leading foot did not pass the toe of the trailing foot by more than one inch. As a result, you required 13 minutes longer than your previously demonstrated ability to deliver mail to this section of your route."

From a letter sent in July from the U.S. Postal
Service to Martha Cherry, an 18-year veteran
mail carrier in White Plains, New York.
The Executive Newsletter (February 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Cancer Gene Testing?

Letter to the Editor: We read with interest the recent article "Do Physicians Discuss Genetic Testing with Family-history-positive Breast Cancer Patients?" (*Conn Med* 1998; 1:3–7). As Dr. Polednak correctly reviews, genetic assessment and testing for hereditary cancer are complicated endeavors and should only be undertaken in context of appropriate genetic counseling covering the risk, benefits, limitations, and psychological and social implications inherent in cancer gene testing. We would like to point out that in this state Cancer Genetics Programs specifically providing these services have been available at the University of Connecticut School of Medicine, Yale University School of Medicine, and Stamford Hospital for several years now. Cancer Genetics Programs are generally established as collaborative programs between genetics, oncology, and surgical services, and provide a consultative service to physicians with patients whose histories suggest the presence of hereditary cancer. We strongly believe that cancer gene testing should not be undertaken without appropriate pre- and post-test counseling.

Robert Pilarski, M.D.
Genetic Counselor and Coordinator
Cancer Genetics Program
Robert M. Greenstein, M.D.
Professor of Pediatrics
Director, Division of Human Genetics
University of Connecticut School of Medicine

So What About Character?

Letter to the Editor: To answer your question "What About Character?" (*Conn Med* 1998; 62:103), what about it? What is it? What is it not? Why character in a medical journal? Why Bill Clinton as emblematic of the decline of values since the 1960s?

Your definition of "the ancients" as including "almost everyone up until the 1950s" suits me fine. Half the people I know never heard of Lamont Cranston. It wasn't until 1957 that J. Edgar Hoover was forced to admit the existence of organized crime, according to William Roemer, FBI agent—author of *War of the Godfathers.* In the happy 1950s the FBI wasn't counting crime stats. J. Edgar did not concern his FBI with "evil that lurks in the hearts of men." But the Shadow (Lamont Cranston) knew.

Luc Sante, in *Low Life,* describing New York City in mid-19th century, said one could fire a shotgun in any direction at the corner of Broadway and Houston, and never hit an honest man. At the end of the Victorian Age, by the time Broadway was paved to 42nd Street, one could shout, "There goes the man who stole my watch!" and a dozen men would run off in different directions. I've seen *Titanic* on film and stage, and I'm happy to report nearly a century later that we are as pretentious and flawed as they were then. Women, children, and first-class men to the life boats! Character is only revealed when tested, whether post-Victorian or post-Modern.

Were "classical virtues" manifest in the Victorian Age? I suspect humans were as human then as now, the Queen and Royals included. Diogenes in classical Greece took his lamp in search of an honest man. "The liberating '60s" are too readily viewed as beginning the decline in values, when our campuses were attacked by students opposed to war in Viet Nam, when Abby Hoffman shouted "Man loves war, like linguini," and Bill Clinton made the Oxford drug scene by lighting a roach. The murder of Kennedy, lies of Johnson, and eventual exposure of Nixon turned us into political cynics, at one with Diogenes the original Cynic. My wife and I adopted an infant son Benjamin, born in Viet Nam, now a young man, an artist, and joy to all who know him. This had nothing to do with "the classical virtues of prudence, courage, wisdom, and justice." Our adoption of Ben was an expression of desire, not value. Values may change, but desire is as old as the hills.

Bill Clinton crossed the Rubicon when he rented out Abe Lincoln's bedroom, after which any sin is possible. Now we turn away from politicians, even quintessential Bill Clinton, as we search for character under the lamp of Diogenes. Not out of virtue but from natural desire women and children are first to the life boats. Simply put, they are our future. Out of natural desire we turn to physicians, to save us from disease and pain if not from death, and comfort us when our rainy day inevitably comes. Doctors ought to know what character is. It is not merely taking an Oath when the medical degree is conferred. What is character? It is a battle hard-won; it puts lines on the face, lines that won't be crossed, marks that connect the soul to eternity. Character is honor, lived to the end, born on the battlefield of human desire, never sacrificed, never relative, always with purpose, in spite of the times in which we live and serve. It is exactly this that must be restored to our profession.

Charles W. Needham, M.D.
Norwalk

From the Executive Director's Office

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1998 Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway. Meriden. The meeting will commence at 12:30 P.M. on Wednesday, 13 May and will continue until all business has been concluded. Governor Rowland and Mrs. Barbara Kennelly have been invited to speak at the meeting.

Stanley J. Keating, M.D., President
Howard J. Wetstone, M.D., Speaker of the House
John P. Bigos, M.D., Secretary

11:30 A.M.	Luncheon and Registration of Delegates
12:30 P.M.	Call to Order
	Adjournment at Conclusion of Business
	Reception for the Incoming President

MEMBERS OF THE HOUSE OF DELEGATES

The President of the Society
The President-Elect of the Society
The Vice-President of the Society
The Secretary of the Society
The Treasurer of the Society
The Speaker of the House of Delegates
The Vice-Speaker of the House of Delegates
The Delegates and Alternate Delegates to the American Medical Association
Councilor-at-Large
Councilors and Associate Councilors
County Delegates

All past-presidents of the Society and alternate delegates are ex-officio members of the House of Delegates without the privilege of voting. (Complete lists of delegates were not available from the county associations in time for publication in this Handbook.)

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member, or Postgraduate physician Member of The Society in compliance with the following provisions:

a. *All resolutions, reports, and similar items of business submitted in writing and received at the office of the Executive Director not later than 30 days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than 35 days prior to the date of the House of Delegates shall be allowed five days after the close of such meetings in which to submit resolutions, reports, and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than 15 days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions, or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred as once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

IN MEMORIAM

BIRNBAUM, HYMAN B., Royal College of Surgeons of England, 1935. Dr. Birnbaum, a general practitioner, was on the staff of Yale New Haven Hospital from 1945 to 1970. He was Madison's director of health from 1954 to 1959. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Birnbaum died 21 March 1998 at the age of 87.

CAMPBELL, ROBERT H., Wayne State University School of Medicine, 1935. Dr. Campbell first practiced general medicine in St. Clair, Michigan. In 1948, after completing a residency in Obstetrics and Gynecology, he moved to West Hartford and was on staff at Hartford Hospital. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Campbell died 19 February 1998 at the age of 89.

COLEMAN, ROGER L., Tufts University School of Medicine, 1971. Dr. Coleman, a psychiatrist, joined the State of Connecticut Department of Mental Health and Addiction Services as Chief of Professional Services at Cedarcrest Hospital, Newington in 1992. Additionally, he served as Acting Chief of Professional Services at Capitol Region Mental Health Center from 1993 to 1995. Dr. Coleman was a founding director of the Psychiatric Inpatient Unit at Danbury Hospital, and later served as the Director of the Division of Psychiatry at Veterans Memorial Medical Center, Meriden. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Coleman died 29 January 1998 at the age of 52.

GORHAM, GRACE V., University of Michigan Medical School, 1930. Dr. Gorham began her private practice of obstetrics and gynecology in Norwalk in 1934. She was a senior-attending member of the Norwalk Hospital Staff until her retirement in 1979. She also served as the first woman to head the Department of Obstetrics and Gynecology at Norwalk Hospital during World War II. Past president of the Norwalk Medical Society, Dr. Gorham was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Gorham died 22 February 1998 at the age of 96.

HEALY, THOMAS MCLEAN, Columbia University College of Physicians and Surgeons, 1941. Dr. Healy practiced general surgery at Manchester Memorial Hospital from 1952 to 1982, and later retired as a medical consultant for the Aetna Life Insurance Company. He was the former chief of surgery at Manchester Memorial Hospital. Past president of the Manchester Medical Society, Dr. Healy was a member of the Hartford County Medical Association where he served as a delegate to the Connecticut State Medical Society during the 1960s, and the Connecticut State Medical Society. Dr. Healy died 22 February 1998 at the age of 82.

KAPLAN, STEVEN C., Ross University School of Medicine, Dominica, 1983. Dr. Kaplan maintained a private practice in Manchester specializing in pediatrics and adolescent medicine. From 1994 to 1997, he served as chairman of the Department of Pediatrics at Manchester Memorial Hospital. He was an assistant clinical professor of pediatrics at the John Dempsey Hospital of the University of Connecticut School of Medicine. Dr. Kaplan served on the pediatric staff of the Connecticut Children's Medical Center. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Kaplan died 24 February 1998 at the age of 41.

KEAVY, WILLIAM T., Marquette University Medical School, 1963. Dr. Keavy, a reconstructive and plastic surgeon, was on the staff at Lenox Hill Hospital and Doctors Hospital in New York City and St. Joseph's Hospital in Stamford. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Keavy died 26 March 1998 at the age of 62.

SCHWARTZ, SOLOMON S., Tufts University School of Medicine, 1946. Dr. Schwartz was a radiologist who, throughout his career, was involved in teaching, research, and practice at the Brooklyn Jewish Hospital, New York University, Yale, and The Hospital of St. Raphael. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Schwartz died 15 January 1998 at the age of 77.

SHERWOOD, HENRY, New York Medical College, 1937. Dr. Sherwood initially practiced medicine in Durham then relocated to Middletown. He was the physician for the Middletown Public School System for several years. Following a residency in allergy, Dr. Sherwood specialized in the practice of allergy in Middletown until he retired in 1977. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Sherwood died 22 February 1998 at the age of 86.

SPINNER, SAMUEL, Tufts University School of Medicine, 1935. Dr. Spinner, an internist, practiced in New Haven until his retirement in 1988. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society where he had previously served on the Editorial Board of Connecticut Medicine and the Committee on Medical Economics and Insurance, and the American Medical Association. Dr. Spinner died 22 September 1997 at the age of 86.

TATE, CURTIS E., University of Kansas School of Medicine, 1970. Dr. Tate was the head of Waterbury Hospital's Henry S. Chase Outpatient Center. For 20 years, he maintained a private practice at Watertown Medical Associates. He was affiliated with Waterbury Hospital for many years and last year became

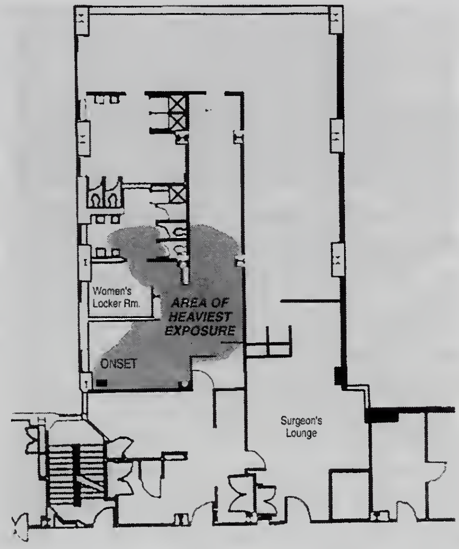
IN MEMORIAM *continued*

director of the outpatient center there. Dr. Tate was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Tate died 19 February 1998 at the age of 53.

ZIGUN, CHARLES, Yale School of Medicine, 1956. Dr. Zigun maintained a private psychiatric practice in Fairfield for over 30 years and was affiliated with the greater Bridgeport Mental Health Center as a staff psychiatrist for five years. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Zigun died 5 March 1998 at the age of 68.

CORRECTION

In the February issue of *Connecticut Medicine,* the article entitled ***Noxious Fumes in a Medical Center: Chemical and Psychological Aspects*** by Elihu York, M.D., Michael J. Hodgson, M.D., Brian W. Cooper, M.D., and Charles A. McKay, Jr., M.D., the figure shown below was inadvertently left out of the article.



The Physician Health Program

- The **PHP** recognizes that most people may not know what to do when they suspect that a physician may be impaired, or how to help him.
- Referrals are accepted and come from many sources including colleagues, patients or friends, family members, and often from the affected physicians themselves.
- Referrals to the **Physician Health Program** are confidential, and experienced help is only a phone call away.

The **Physician Health Program** is a service of the Connecticut State Medical Society

For more information or to call in confidence, contact the **PHP** at (203) 865-0587 or 1-800-635-7740

Neil J. Grey, M.D.
Medical Director

Michele R. Norbeck
Director

A confidential, effective, compassionate and responsible approach towards recovery

BOOK REVIEWS

Message in a Bottle:
Stories of Men and Addiction
by Jefferson A. Singer, 256 pp,
New York, The Free Press, 1997
$25.00 ISBN: 0-684-82720-4

The all too common problem of chronic relapsing chemical dependency despite repeated detoxification, numerous exposures to both short- and long-term inpatient treatment, involvement with the 12-step programs, and halfway house monitoring is a source of bitter disappointment and profound frustration not only for the addict who has sought or has been referred for help but also for professionals working in the field. The intractability of addiction and its persistence despite varied efforts to alter its course contribute to the bias, stigmatization, discrimination, and societal isolation of those who suffer from it.

Singer, in a clear, concise, and elegant work, records the histories of male dependent recidivists noting their failure to form an identity capable of ameliorating the anxiety of an existence without meaning, devoid of a sense of freedom, and pervaded by fear of death and isolation. Negative social and cultural factors obviously play a role in the failed maturation of positive identity and the lack of development of worthy goals and a sense of sharing in community. The developmental backgrounds of the men interviewed by Dr. Singer dramatically point to the ill effects of racism, homophobia, the broken home in which there is drug/alcohol abuse and, spousal and child abuse are commonplace, violence—witnessed, experienced, and perpetrated—and the pervasive, dehumanizing secular materialism and consumerism that characterize current society in America.

Singer suggests possible solutions that may be productive of better treatment outcomes for end-stage dependency. These involve inducing a feeling of hope coupled with the development of post-treatment programs to eliminate isolation and disconnection from society, to reintegrate our addicted brothers and sisters into the workplace, and to provide them with a stable living environment—a place they can call *home*. This book must be read by all of us in the drug/alcohol policy and treatment field.

Henry N. Blansfield, M.D.
Danbury

Surviving the Fall: The Personal Journey
of an AIDS Doctor
by Peter A. Selwyn, M.D., xxi, 145 pages,
New Haven: Yale University Press,
ISBN 0-300-07126-4 (Cloth)

We recall, perhaps with a start, that AIDS has been "with the people" (that is what *epidemos* means) for a mere 17 years and, it is fast becoming an endemic chronic disease throughout the world. A young physician entering the world of medicine in 1981 with the AIDS epidemic is still a young physician, barely in mid career.

Peter Selwyn, graduated from Harvard Medical School in 1981, in the very month when the first cases of a new syndrome among homosexual men was reported by the CDC, and began his family medicine residency at Montefiore. He was soon, to use his word, immersed in the rising flood of drug abuse and AIDS. As he recounts the story of his decade in the Bronx on the staff of Montefiore Medical Center, first as resident, then as medical director of the methadone program, we relive with him those scary years as the epidemic grew from being a new disease complex in homosexual males, Haitians, and hemophiliacs, to becoming the disease of the century. In our hubris we had predicted in the 1970s our coming farewell to infectious diseases, at least in the developed world. Dr. Selwyn takes us through the years of that decade, most memorably by narrating the life stories of many of his patients.

In his introduction to *Surviving the Fall*, Sherwin Nuland prepares us for Selwyn's message: medicine is mostly about our patients and their families, their fears, their pain, their bravery, their strength, their weakness, their leave-taking, and their dying. The rest that we doctors do is to manage an imperfect technology, and at times become so enamored of it that we forget about why we are there in the first place. Dr. Nuland writes:

> The fault I so lament is the product of the single greatest problem facing a profession in which compassion, empathy and dedication to a pastoral calling have long been idealized as the traditional hallmarks of commitment to the relief of human suffering, even though they have for the most part been incompletely attained. Medicine's and my great problem and great fault consist in what might be called intellectualization—the enrapturement with science and technology—by which that legion of men and women who are today's doctors have allowed themselves to become besotted (ix-x).

Faced with a disease like AIDS for which technology had so little to offer, a young physician "besotted" with science and technology, might well say this is not for me and apply for a Ph.D. program in immunology or a residency in radiology. And indeed not for all is the pastoral calling of medicine; science and technology constitute part of the glory of the 19th and 20th centuries, and may even one day eliminate such formidable killers as AIDS, tuberculosis, and malaria. As Lewis Thomas more than once remarked, the high technologies of medicine are generally simple and cheap—a perfect antibiotic, a 100% effective vaccine. Even then, the need for the "pastoral calling" of medicine will remain, even more than ever when the technology becomes simple and cheap.

Selwyn likens his account of the early days of the AIDS epidemic to Daniel Defoe's *Journal of the Plague Year*; during London's Great Plague of 1665; as during the early years of AIDS, there was little to be done except to care for the dying and to record the names of the dead. His telling of the story of these years recalls for me, both in style and substance, Albert Camus' *The Plague*.

The title, *Surviving the Fall,* turns out to be a metaphor for Selwyn's profoundly personal encounters with the tragic lives of his patients, the deaths of young mothers and fathers, the orphaning of children, the tearing apart of families. While he wrote of the need for detachment, as William Osler did for *æquanimitas,* his patients' lives became entwined with his very being.

His own father had died when he was 18 months old, was said to have fallen out of a high window in a building in Manhattan. Suicide? His mother spoke little about it; again and again his questions were turned aside, but recurring thoughts of his father's unexplained abandoning of his 18-month old son was for him "a sign of [my] own unresolved pain ... buried under layers of denial, socialization, and professional competence."

The final chapters in *Surviving the Fall,* "Connections," "Excavation," and "Reconstruction," troubled me because they were so very personal. That is partly my own problem; for a member of Selwyn's father's generation the very idea of revealing to strangers such deeply held, but only imperfectly understood, feelings simply was not done, perhaps even to oneself and never in public. Yet in a workshop at the Elisabeth Kübler-Ross Center he did exactly that.

> My personal journey through my own history and back again was prompted, in part, by the countless small ways in which my work experience as a physician in the AIDS epidemic kept bringing me back to the central, unresolved issue of my life.... Once I became aware that I had never come to terms with the loss of my father, I began the work of grieving both for my father, which I had never done, and for all my patients who had died.

He completed his journey in a way satisfying both to himself and to his reader: "I survived the fall.... and walked upstairs and out the door into the bright, afternoon sunlight."

In 1992 he and his family moved to New Haven where he is associate director of the AIDS program and associate professor at Yale University School of Medicine.

Robert U. Massey, M.D.
Avon

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy. Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

***Opportunities* should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians making inquiries of such *opportunities*.**

***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

Announcements on the Physician Placement Service page under Classified Advertising are charged at the regular Classified Advertising rate.

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Busy, cheerful gynecology practice seeks board certified ob/gyn for gynecology only. Full- or Part-time in comfortable well staffed office. Send CV to: Brunilda Castillo, Office Mananger, 2 Church Street South Suite 501, New Haven, CT 06519.

PART-TIME

Physician wanted for part-time employment every other weekend and occasional evenings for urgent care center located in central Connecticut. Please respond to: CSMS c/o PT/RS.

M.D. wanted part-time, flexible hours for multidisciplinary clinic in Bristol, Connecticut. Must be holistically inclined. Call (860) 583-0516 or fax CV to (860) 583-0667.

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Primary care/internal medicine physician wanted to join Hartford area M.D. with an office and hospital based practice. Please call Subrata K. Basu, M.D., telephone (860) 278-8641.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

INTERNAL MEDICINE

Board eligible internist; CT license; immediate availability (locum tenens/permanent); seeking primary care office based practice setting. Prefer outpatient/clinic/urgent care. Contact: Wm. DiFederico, M.D., (203) 375-2912.

American Board certified internist. Connecticut license, ACLS. Trained at Hartford Hospital/University of Connecticut. Proven record of high quality cost effective medical care and patient satisfaction. Would like to join an office based internal medicine or urgent care group, associates or institutional practice. Please contact Richard A. Graniero, M.D. Telephone/fax (860) 395-1530.

Available immediately. Licensed in New York. Passed National boards, American board certified. M.D. at NYU. Internship and residency at NYU/Bellevue Hospital, chief resident 1994-1995. Would like to join a group practice in Southern Connecticut. Please respond to CSMS c/o IM/TL.

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Available immediately. Licensed in Connecticut, Maryland, and New York. Passed National boards. American board certified. M.D. at University of Connecticut. Internship and residency at St. Mary's Hospital, Waterbury. Fellowship at Johns Hopkins, Baltimore. Would like to join an institutional or industrial practice. Please respond to: Malinda Midzenski, M.D., 25 Van Rose Dr., North Haven, CT 06473, telephone (203) 248-7929.

PAID CLASSIFIED ADVERTISING

All PAID classified advertising orders, correspondence, and payments should be directed to: CONNECTICUT MEDICINE, Classified Department, 160 St. Ronan Street, New Haven, CT 06511, Tel. (203) 865-0587. The Classified rates are as follows: $60.00 for 25 words or less; plus $1.00 each additional word. For confidential answers, the cost is $3.00 per insertion, sent in care of CONNECTICUT MEDICINE. Ad copy must be typewritten, double spaced, with payment, and delivered no later than the first day of the month preceding the month of issue.

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18th Annual Emergency Medicine Seminar

**Contemporary Concepts in Clinical
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Consumer Concern Or Complaint Form
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Including Managed Care Plans

To Be Submitted To
THE CONNECTICUT DEPARTMENT OF INSURANCE
CONSUMER AFFAIRS DIVISION
P.O. BOX 816
HARTFORD, CT 06142-0816

Phone: (860) 297-3900 or 1-800-203-3447 Fax: (860) 297-3872

The Consumer Affairs Division of the Department of Insurance receives, reviews and responds to complaints and inquiries from state residents concerning insurance related problems. The staff examines each complaint to determine whether statutory requirements and contractual obligations within the commissioner's jurisdiction have been fulfilled. The Consumer Affairs Division coordinates the resources available within the Department to address consumer complaints.

In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

Name of person filing the concern or complaint:

____

Address: ____________________________________

Phone where the Department can contact you: (_____) ____________________

This concern or complaint concerns the following Insurance Company or Managed Care Plan: ____________________________________

Policy Number: ____________________________________

Name of Policyholder: ____________________________________

Name of Enrollee: ____________________________________

Name of Patient: ____________________________________

Patient is ___ self ___ dependent ___other (explain)____________________

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 MAY 1998 NUMBER 5

scientific:

Robert Wolek, Brian J. Mason, Pamela Reeser, and Jonathan H. Zins 259 **Pleural Fluid: Accuracy of Computed Tomography in Differentiating Exudates from Transudates**

Epitomes of Progress
Leon I. Thal 267 **Important Advances in Clinical Medicine—Neurology**

The Medical Letter
279 **Advice for Travelers**

Drug Information Update: Hartford Hospital
Gale Tucker 283 **Atorvastatin (Lipitor®)**

special articles:

Sheryl Gay Stolberg 287 **As Life Ebbs, So Does Time to Elect Comforts of Hospice**
Stephen R. Levinson 291 **The AMA's Evaluation and Management Coding Conference of 27 April 1998**

commentary:

Randy A. Goodwin 295 **Back to the Bedside**
Charles W. Needham 295 **Science and Sense**
Anthony P. Redmond 296 **Malpractice Coverage in Connecticut for the Last 30 Years**
Richard L. Newman 297 **Physician Liability for Suicide of Noncustodial Patients**

departments:

Fifty Years Ago
301 **Medicine in a Planned Economy**

The President's Page
Stanley J. Keating, Jr. 303 **Memorial Day**

Reflections on Medicine
Robert U. Massey 305 **On Words, Style, Grammar, and Other Matters**

Medical News Capsules
Timothy B. Norbeck 307 **This Month's Reading in Review**

CPRO Corner
Ken Roberts 309 **CPRO Focus Now on Quality Improvement Collaboration**

Letters to the Editor
Anthony P. Polednak 311 **Regarding: "Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Review of the Connecticut State Tumor Registry"**
Khalique S. Zahir and Stanley J. Dudrick 311 **Drs. Zahir and Dudrick Respond to Dr. Polednak**
Edward J. Volpintesta 312 **Burdensome Medicare Guidelines**
Saeeda Chowdhury and Stephen Atlas 313 **Leg Edema Secondary to Bladder Distention**

From the Executive Director's Office
CSMS 315 **Council Minutes**

general:

318 **CSMS Physician Placement Service**

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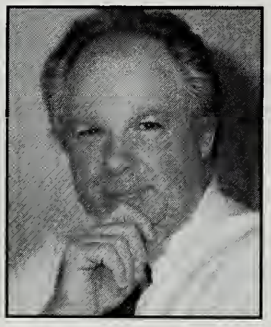

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Pleural Fluid: Accuracy of Computed Tomography in Differentiating Exudates from Transudates

ROBERT WOLEK, M.D., BRIAN J. MASON, M.D., PAMELA REESER, M.D., AND JONATHAN H. ZINS, M.D.

ABSTRACT—*Purpose:* To determine the accuracy of computed tomography in differentiating pleural exudates from transudates when reviewed subjectively by two experienced radiologists in a community hospital.

***Methods:* Computed tomography scans of 55 consecutive patients who had a thoracenteses within 10 days of the study were retrospectively reviewed independently by two experienced staff radiologists. They were asked to evaluate subjectively parietal pleural thickness (anterior, lateral, posterior), attenuation of extra-pleural fat, and categorize pleural fluid as loculated or free flowing. Radiographic findings were correlated with biochemical results of thoracentesis (Light's criteria) to assess the accuracy of computed tomography in differentiating pleural exudates from transudates.**

***Results:* For the diagnosis of an exudate, pleural thickening alone had the best sensitivity and specificity (50%, 100%, respectively) with an accuracy of 55%.**

***Conclusion:* Subjective evaluations for increased pleural thickness have a high accuracy for diagnosing pleural exudates.**

Introduction

IN a recent article by Dr. Suzanne L. Aquino et al, the accuracy of computed tomography (CT) in differentiating pleural exudates from transudates was ascertained.[1] Her group found that parietal pleural thickening on contrast enhanced CT almost always indicates the presence of exudate (sensitivity 61%, specificity 96%, positive predictive value 97%, negative predictive value 54%). Actual measurements of pleural thickness were performed on the scans during the study. In their study, 2 mm was established as the upper limit of normal pleural thickness. Since many diagnoses in radiology are based upon the radiologist's judgment without precise measurements, and the site of measurement of maximum appreciated pleural thickening is a subjective decision, we sought to determine if experienced radiologists (using as baseline the appearance of pleura in normal subjects), could subjectively perform as well as Aquino et al, in differentiating pleural exudates from transudates.

The thickness of normal pleura, including visceral and parietal layers, and the fluid containing pleural space is 0.2 to 0.4 mm. The pleura is therefore difficult to image on CT. The intercostal stripe actually represents the combined density of visceral and parietal pleura, the fluid-filled pleural space, endothoracic fascia, and the innermost intercostal muscle. The combination of these structures is evaluated when pleural thickening is assessed. Other components of the chest wall, such as the subcostalis muscle, intercostal vessels, or transversus thoracic muscle may be confused for pleura and false pleural thickening. However, awareness of these structures and their anatomy should prevent such errors.[2]

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Table.—Average Performance of the Two Radiologists in Interpreting Nonenhanced Scans.

Nonenhanced Scans	Anterior Pleural Thickening	Lateral Pleural Thickening	Posterior Pleural Thickening	Loculation	Increased Fat Attenuation
Sensitivity	21%	34%	46%	47%	3%
Specificity	80%	80%	80%	80%	100%
Accuracy	32%	43%	52%	53%	21%
Positive Predictive Value	82%	88%	91%	91%	100%
Negative Predicitve Value	20%	22%	25%	25%	19%

Average Performance of the Two Radiologists in Interpreting Enhanced Scans.

Nonenhanced Scans	Anterior Pleural Thickening	Lateral Pleural Thickening	Posterior Pleural Thickening	Loculation	Increased Fat Attenuation
Sensitivity	32%	41%	50%	44%	6%
Specificity	100%	100%	100%	100%	100%
Accuracy	41%	49%	55%	51%	18%
Positive Predictive Value	100%	100%	100%	100%	100%
Negative Predicitve Value	18%	21%	24%	22%	14%

Material and Methods

Enhanced and nonenhanced CT scans of 55 consecutive patients with thoracenteses were retrospectively and independently reviewed by two experienced radiologists. Forty-five patients had both enhanced and nonenhanced scans. Ten patients had only nonenhanced scans. Three normal CT scans were used as controls. Parietal pleura in anterior, lateral, and posterior locations was subjectively assessed for thickening. Effusions were further categorized as free flowing or loculated. The attenuation of the extra-pleural fat between the pleura and ribs was described as equal to subcutaneous fat, equal to chest wall muscle, or intermediate in density. Right- and left-sided effusions in the same patient were evaluated separately.

Thoracenteses were performed within a 10-day window before or after the CT. The side of the procedure and the results of the laboratory values including lactate dehydrogenase (LDH) and total protein concentration of the pleural fluid and pleural fluid culture and cytology were reviewed. As in the previous article, the original Light's criteria were used to classify the aspirated pleural fluid as either transudates or exudates.[3] At least one of the following criteria was met to classify an effusion as an exudate: a) pleural fluid total protein/serum total protein ratio of more than 0.5, b) pleural fluid LDH/serum LDH ratio of more than 0.6, and c) pleural fluid LDH greater than two-thirds of the upper limits of normal for serum LDH.

The biochemical results were correlated to the accuracy of CT in differentiating pleural exudates from transudates. The average sensitivities, specificities, accuracies, positive predictive values, and negative predictive values of the readers were determined.

Results

The sign with the highest sensitivity appears to be posterior pleural thickening on enhanced scans (sensitivity 50%, specificity 100%, positive predictive value 100% and accuracy 55%) followed by loculation on nonenhanced scans (sensitivity 47%, specificity 80%, positive predictive value 91% and accuracy 53%). The positive predictive value for any pleural thickening or loculation on enhanced scans was 100%. However, the negative predictive value at best was 25% for posterior pleural thickening or loculation on nonenhanced scans. Thus while an enhanced CT scan can be diagnostic for the presence of exudate, more importantly, it may not be used at this time to exclude its presence.

There were 13 malignant effusions. Twelve had nonenhanced and enhanced scans available. All of the malignant effusions were exudates. In these cases, enhanced scans with posterior pleural thickening or loculation had the best sensitivity for exudates. Forty-six percent of malignant effusions had posterior pleural thickening. Based on the results of aspirates, we recognize that patients may well have had an underlying malignancy with associated tran-

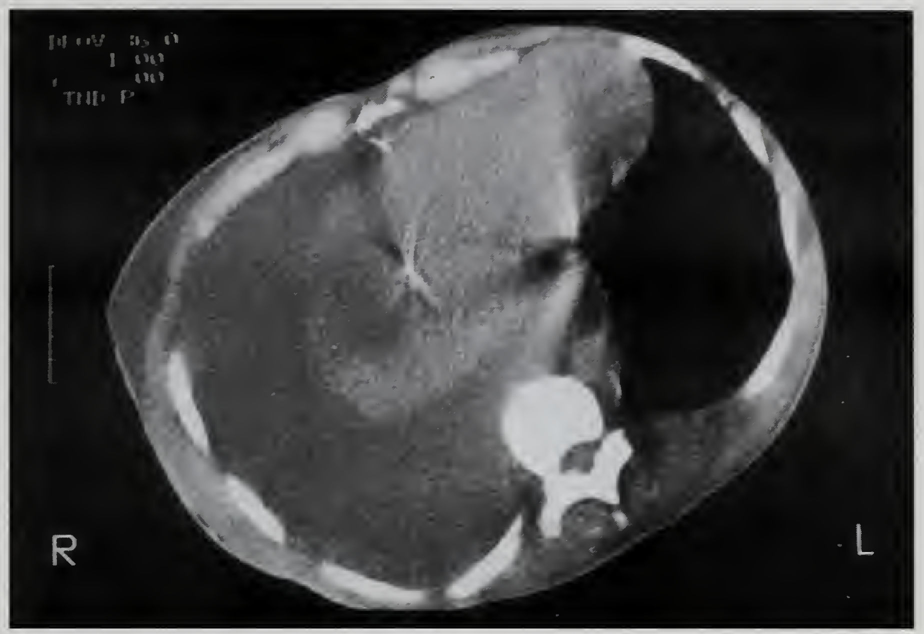
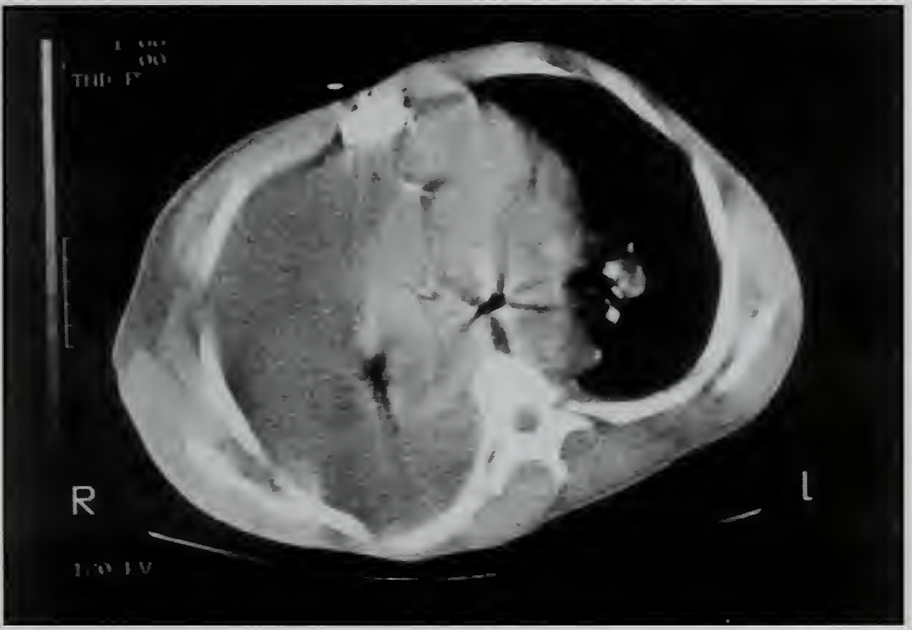


Figure 1 and 2.—Right inflammatory exudate, false negative resulting from the lack of pleural thickening and absence of pleural fluid loculation.



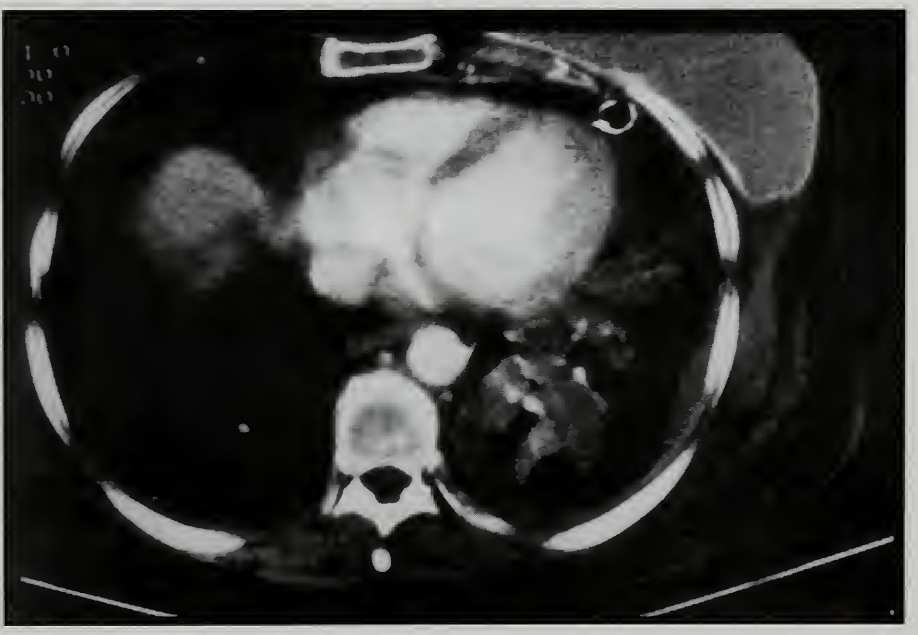


Figure 3.—Left malignant exudate, true positive due to the presence of pleural thickening and pleural fluid loculation.

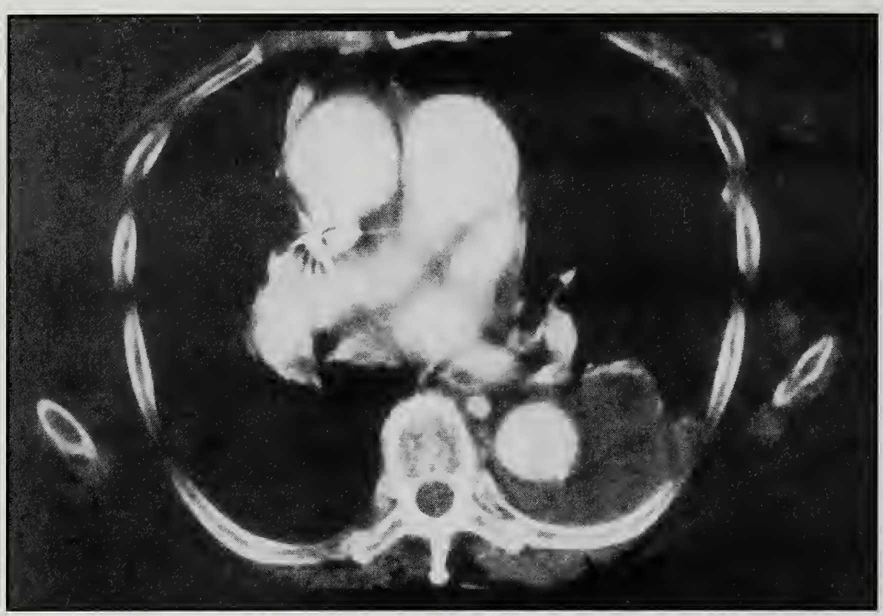


Figure 4.—Left malignant exudate, false negative resulting from the lack of pleural thickening but true positive due to the presence of pleural fluid loculation.

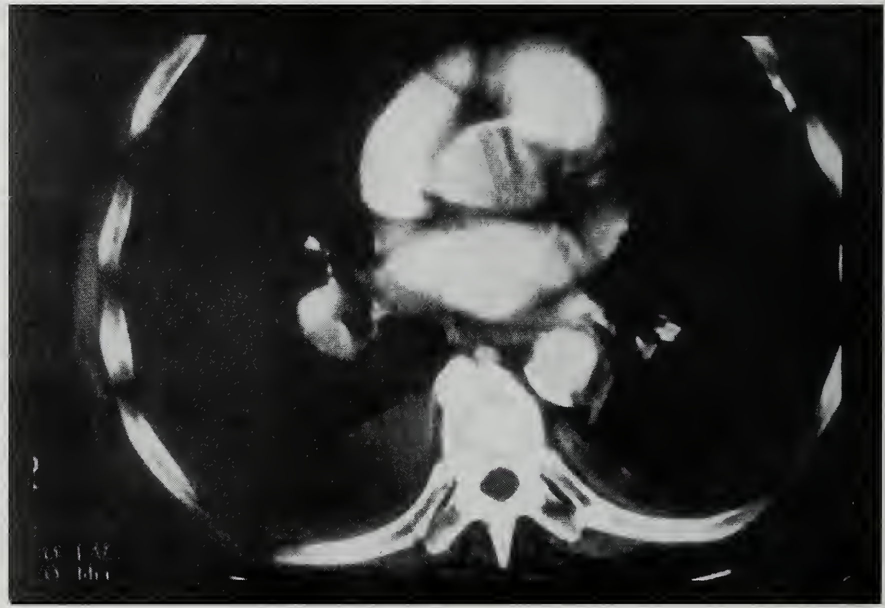


Figure 5.—Right exudate, true positive due to the presence of pleural thickening but false negative due to the lack of pleural fluid loculation.

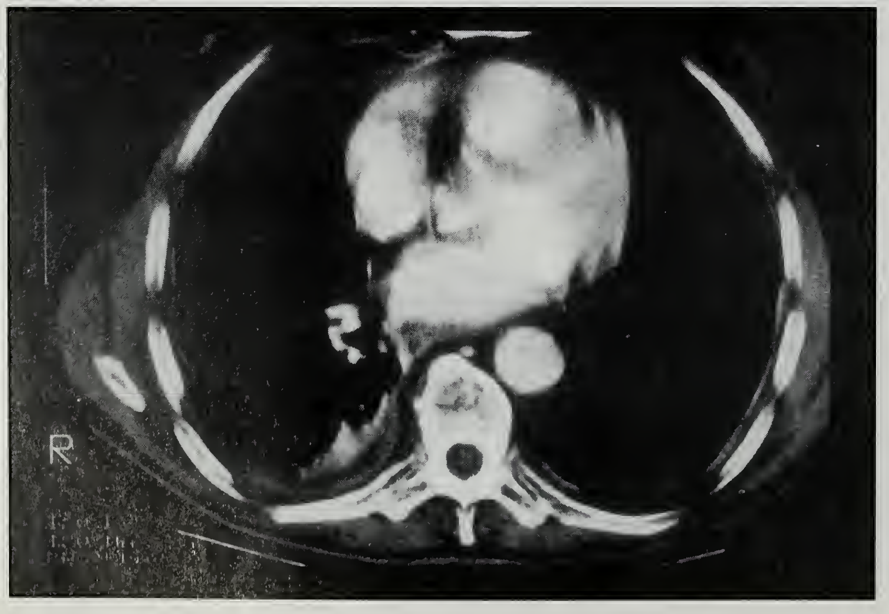


Figure 6.—Right inflammatory exudate, true positive due to the presence of pleural thickening but false negative resulting from the lack of pleural fluid loculation.

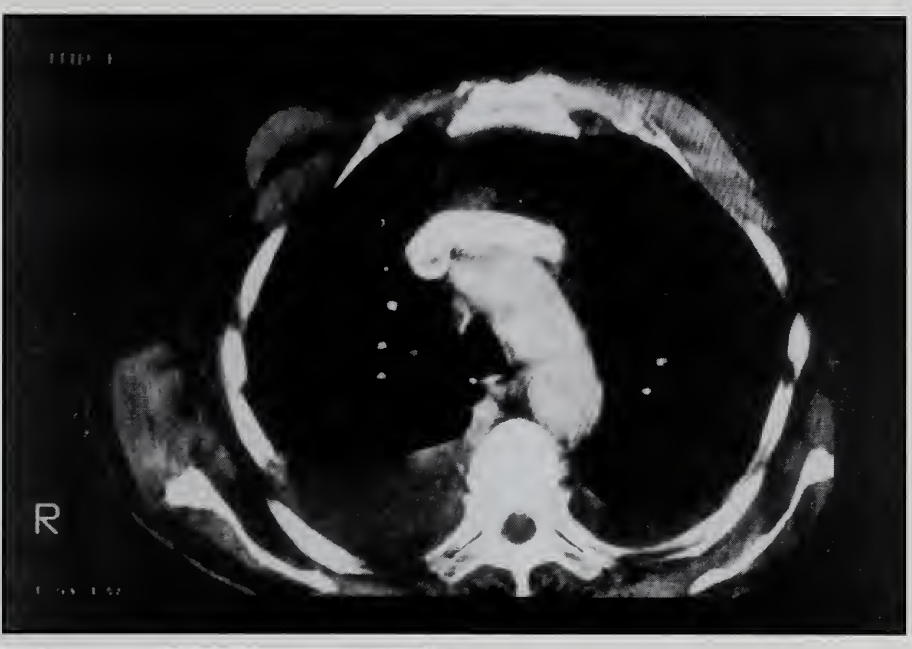


Figure 7.—Left transudate, true negative due to the lack of pleural thickening and lack of pleural fluid loculation.

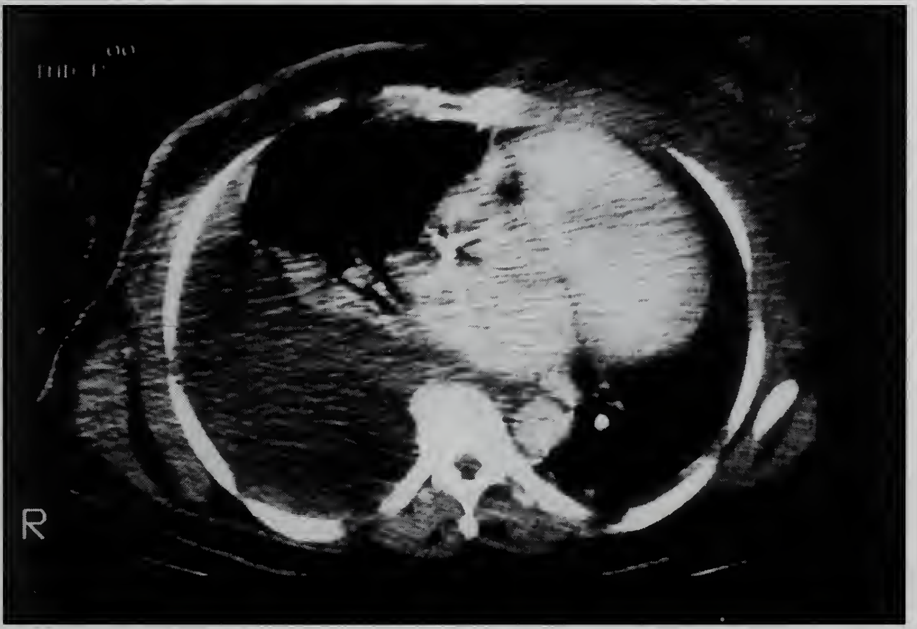


Figure 8.—Right inflammatory exudate, false negative resulting from the lack of pleural thickening and lack of pleural fluid loculation.

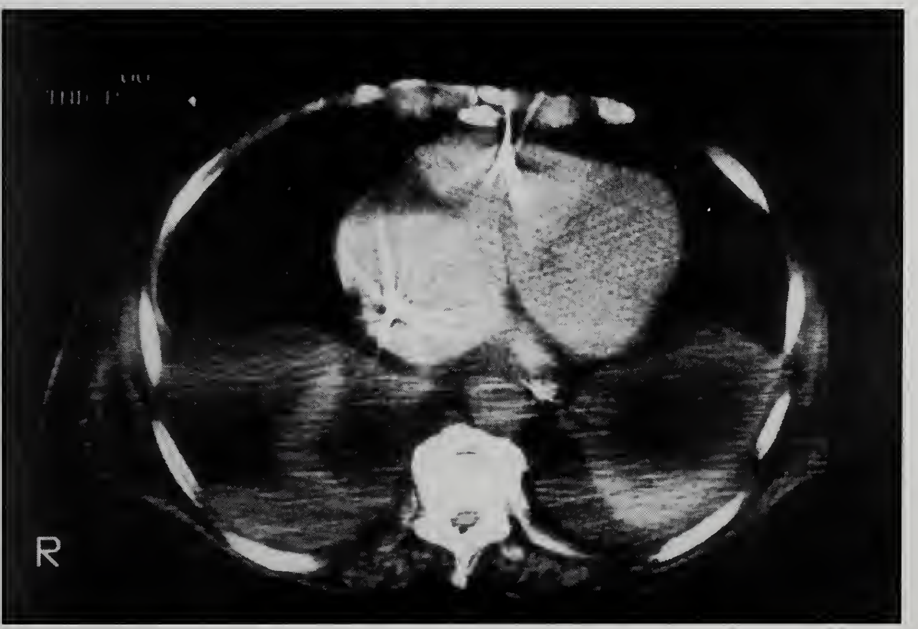
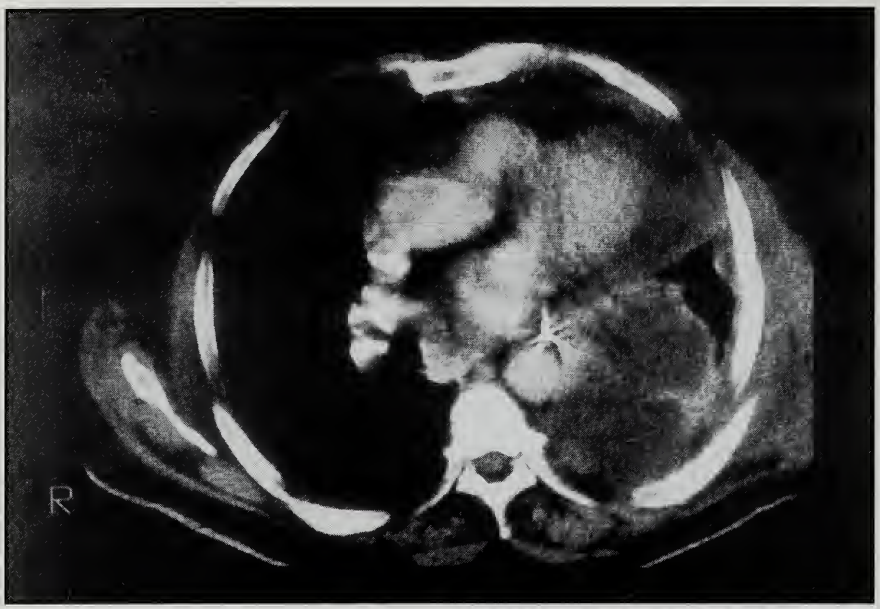


Figure 9.—Right transudate, true negative as evidenced by lack of pleural thickening and pleural fluid loculation.



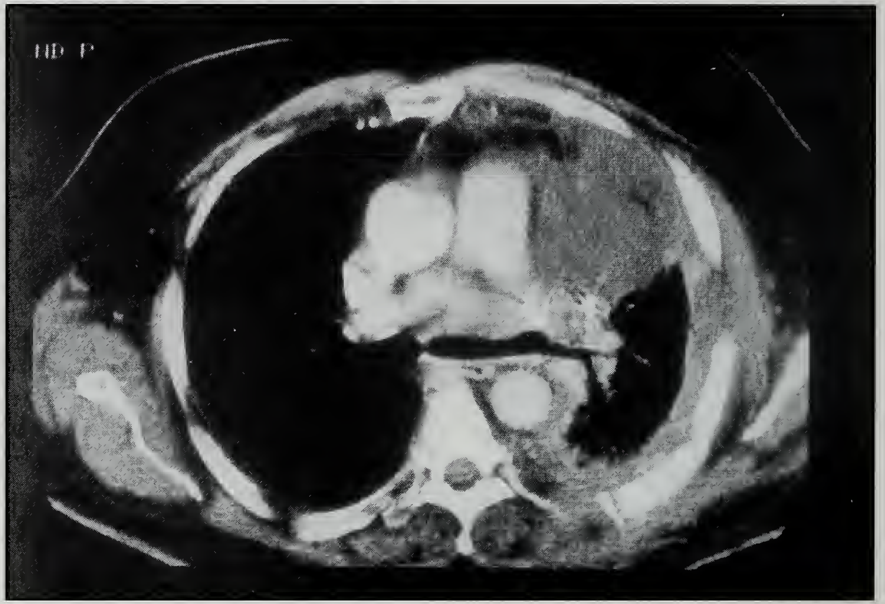


Figure 10 and 11.—Left exudate, true positive as demonstrated by the presence of pleural thickening and pleural fluid loculation.

sudates and negative cytologies. The study did not account for such possibilities, as this was not the goal of this investigation.

There were nine exudates with positive cultures. Enhanced scans with posterior pleural thickening or loculation had the greatest sensitivity for identifying these. Based on the pathology reports, there were two empyemas, one of which was correctly diagnosed on the basis of CT. All of the subjective criteria (pleural thickening, loculation, and increased fat attenuation), were noted in this case.

Discussion

Clinically, a transudate is of less importance than an exudate and probably needs no further investigation or treatment. A transudate may be due to increased hydrostatic pressure resulting from cardiac disease, due to decreased colloid oncotic pressure resulting from hepatic, renal, or alimentary track disease, or due to interstitial fluid drainage impairment. Generally, transudates require therapeutic drainage only when extremely large.

The exudate is clinically more ominous. An exudate may be the result of malignant disease, infection, endometriosis, pancreatic disease, as well as other etiologies. Many exudates require interventional treatment, either drainage, pleuracentesis, or both.

It would be helpful to the clinician if a radiologist could differentiate pleural exudate from transudate on a noninvasive imaging study. Patients with transudates would be spared thoracentesis. Patients with imaging findings compatible with exudate could be treated in a more timely and definitive fashion.

Sonography has a sensitivity of 66%, specificity of 10.0% and a positive predictive value of 100% for exudates if the effusion is septated, complex, or heterogeneous.[4] Previously, Aquino et al reported CT had a sensitivity of 61%, specificity of 96%, and positive predictive value of 97% in differentiating transudates from exudates.[1] That study used more sophisticated methods, including actual measurement of pleural thickness on the scans. Our study is based on the more subjective interpretation of two experienced radiologists. Their judgment compared well with the results of previous studies (sensitivity of 50% and specificity of 100%) indicating that subjective appreciation of signs of exudative pleural effusion is almost diagnostic with a high positive predictive value, especially on enhanced scans. Nonenhanced scans also fare well in this respect. However, the sensitivity of both scans remains low. Therefore, most effusions that appear as transudates will still need to be sampled to differentiate them from exudates.

Magnetic resonance imaging appears to be superior to CT and sonography in characterizing pleural effusions.[5] With greater utilization and further research it may prove helpful in this respect.

Conclusion

Our study, based on the subjective judgment of two experienced radiologists, compares well with the previous study that more objectively evaluated CT for the presence of exudate. The previous study had a sensitivity for exudate of 61%, specificity of 96%, and a positive predictive value of 97%. Our study had a sensitivity for exudate on CT of 50%, specificity of 100%, and positive predictive value of 100%. Although the sensitivity is lacking in both studies, the specificity is high. If signs of exudate are noted on CT, one can be confident that an exudate is present.

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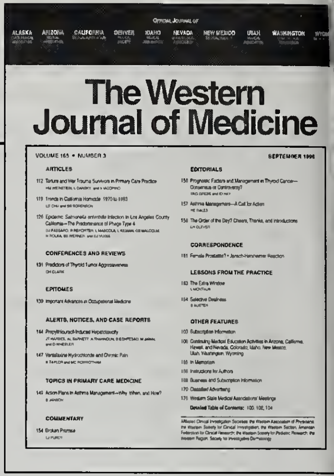

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Important Advances in Clinical Medicine

Neurology

Leon I. Thal, M.D., Section Editors

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in neurology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in neurology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Neurology of the California Medical Association, and the summaries were prepared under the direction of Dr. Thal and the Panel.

Recent Advances in Stroke Therapy

THERE is now unequivocal evidence that thrombolytic therapy with tissue plasminogen activator (tPA) is effective in reducing neurologic damage when administered to stroke victims within three hours after symptom onset. Efficacy is substantial but the treatment regimen is not yet optimal.

In the most definitive study involving tPA, half of the study group patients received treatment within 90 minutes after symptom onset; the rest were treated within three hours. When measured three months after the strokes, highly significant results were obtained in favor of tPA on each of four neurologic rating scales. At least 11% more patients in the tPA-treated group returned to normal neurologic function compared to placebo-treated patients. There was no significant difference in mortality rates, although there was a trend toward decreased mortality rates in the tPA group. There were instances in which hemorrhages in the tPA-treated patients occurred, and they often caused severe injuries or death. Because tPA did not increase the death rate or the extent of neurologic dysfunction (deaths did not change and average neurologic function improved in the tPA-treated group) it can be argued that the benefits substantially outweighed the risks.

Three studies of streptokinase have been halted before the expected time because of disappointing results. There was no convincing evidence of efficacy, and there was a significantly higher intracranial hemorrhage rate associated with the treatment. Patients were entered into the trial up to six hours after symptom onset in these studies, and it is unclear whether patients treated in less than three hours would have benefited. Nevertheless, clinical development of streptokinase for stroke treatment has now ended.

Several aspects of the tPA clinical trial protocols have concerned physicians who are skeptical about the value of this form of stroke therapy. Some have questioned the magnitude of the effects and have suggested that the level of improvement does not justify the increased efforts that are required. Analyses of the data indicate that the relative risk improvement of almost 50% substantially exceeds that for aspirin prophylaxis for stroke. A cost-benefit analysis suggests that tPA therapy for stroke is approximately as beneficial as endarterectomy in patients with high-grade stenosis, and it is much more cost effective than surgical management of asymptomatic carotid stenosis. There is also the question of whether specific types of stroke should be excluded from treatment. The National Institute of Neurological Disorders and Stroke (NINDS) trial data indicate that all types of ischemic stroke either benefit from tPA therapy or had results that were not different from those in the placebo controls. There was no proof that any category of patients was harmed by the treatment. It is possible that future studies will be able to identify categories of patients that will benefit more than others.

It has also been claimed that the results of the NINDS trials cannot be duplicated in private hospitals. The NINDS study was organized at academic centers, but

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many of the patients were recruited in affiliated private hospitals. It remains to be seen whether similar trial results can be obtained in a broader range of institutions, but there is no reason to believe that it is not possible. Presently, almost all patients who can be treated within three hours after symptom onset, who do not have hemorrhages visible on their CT scans, and who do not have blood pressures above 185/110 should receive intravenous tPA.

Numerous other strategies for stroke therapies have been suggested. Neuroprotectives such as glutamate antagonists are intended to minimize tissue damage in the absence of adequate blood supply. Quite a few drugs in this general category are considered promising, and several have been evaluated in clinical trials. Three drugs that block the glutamate receptors were tested in trials that were prematurely terminated when interim analyses indicated there would be no possibility of efficacy and drug-related adverse events occurred. All glutamate antagonists tested in clinical trials have varying side effects, including psychotic reactions and adverse cardiovascular actions. Thus, the doses of these drugs were lowered in the clinical trials to the point at which they were reasonably safe, but it appears that this strategy resulted in the loss of efficacy.

Other drugs that have neuroprotective properties have been tested. These include a free radical scavenger, a white cell antagonist, a GABA agonist, and several drugs that do not have well-defined mechanisms of action in ischemia. Currently no neuroprotective drug has been proven to be effective for acute stroke management.

This is an exciting time in the field of acute stroke therapy. After many years of frustration and failure, we are beginning to treat stroke as a medical emergency. Future clinical trials of other drugs should be facilitated by the demonstrated need to treat stroke patients rapidly. The requirement for urgent delivery of treatment without a thorough preceding diagnostic evaluation makes uncomfortable many physicians who were accustomed to the more deliberate pace of the past. We can now deliver treatments, however, that have an important impact on functional damage. This should be a source of realistic hope for stroke victims and of satisfaction for their physicians.

JUSTIN A. ZIVIN MD, PH.D.
La Jolla, California

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New Approaches to Therapy of Amyotrophic Lateral Sclerosis

AMYOTROPHIC lateral sclerosis (ALS) is a progressive and fatal disease involving degeneration of motor neurons in the spinal cord, brain stem, and cortex. Most patients with ALS die within three to four years of diagnosis, although some live substantially longer. Approximately 10% of ALS patients appear to have a familial form of the disease, but the clinical course and pathology of sporadic and familial cases is very similar. The precise cause of ALS is still unknown, but abundant new evidence supports several theories, including genetic factors, glutamate excitotoxicity, oxidative stress, and possibly diminished neurotrophic factors.

Glutamate is the primary excitatory neurotransmitter in the brain. Glutamate levels are elevated in serum, spinal fluid, and brain tissue of patients with ALS. There is also reduced clearance of glutamate from critical motor control areas in the central nervous system and reduced glutamate transfer protein. The preclinical effects of both riluzole and gabapentin in models of glutamate excitotoxicity and in the transgenic mouse model of motor neuron disease are encouraging. In organotypic cultures of spinal cord motor neurons that model glutamate excitotoxicity, riluzole and gabapentin produced significant neuroprotection. Both drugs prolonged survival in the transgenic mouse model with mutant superoxide dismutase, one of the animal models most closely mimicking ALS. In two randomized controlled clinical trials, riluzole, which inhibits glutamate release, prolonged survival in patients with ALS, albeit to a modest degree (for several months). Riluzole is now the only FDA-approved, disease-specific treatment for ALS. Gabapentin appeared to slow the inexorable weakness in a controlled clinical trial, but the results were not conclusive and a definitive trial is underway. Taken together, these results provide strong support for the role of glutamate excitotoxicity in the propagation of ALS.

The familial form of ALS is generally inherited in an autosomal dominant fashion; in approximately 20% of these patients, there is a mutation in the copper/zinc superoxide dismutase gene (SOD-1). Emerging evidence suggests that the buildup of free radicals plays an important role in pathogenesis. Administration of vitamin E delayed the onset of ALS in the transgenic mouse model, suggesting that oxidative stress may be important in disease initiation. Antioxidants may be helpful for patients, but more studies are needed to confirm their role.

Other therapeutic approaches to ALS involve neurotrophic factors. Preclinical studies with both ciliary neurotrophic factor and brain-derived neurotrophic factor (BDNF) were particularly promising, but large multicenter controlled trials of subcutaneous administration produced no beneficial effect upon the disease. Promising studies with intrathecal BDNP and glial-derived neurotrophic factor (GDNF) are underway. Finally, encouraging results from the U.S. trial of insulin-like growth factor (IGF-1), which show that the decline of function and quality of life for patients with ALS is slowing, are currently under review at the FDA.

Thus, for the first time, there are new, rational approaches to finding treatments for ALS based on a rapidly expanding body of experimental evidence about its pathogenesis. In many ways, ALS has become a prototype for neurodegenerative diseases.

Nonetheless, the mainstay of management is symptomatic treatment. Many options have all helped to alleviate the enormous burden of this disease: percutaneous endoscopic gastrostomy to attenuate weight loss in patients with swallowing difficulty, noninvasive mechanical ventilation to improve airway integrity and sleep, new lightweight mobility aids, and better medication for spasticity, depression, emotional incontinence, and cramps. A North American ALS patient database, launched about two years ago, promises to provide new outcome data that should further raise the standard of care.

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Status Epilepticus

STATUS epilepticus is characterized by abnormally prolonged seizure activity. Although there are numerous forms of status epilepticus that parallel, in part, the various types of isolated seizures, this epitome is directed toward generalized convulsive status epilepticus (GCSE) in adults and older children. GCSE includes the most common forms of status epilepticus (generalized, tonic-clonic, and myoclonic) and is associated with relatively high levels of morbidity and mortality. Because a variety of studies suggest that the typical, isolated tonic-clonic seizure in adults lasts no more that three to four minutes, an operational definition can emphasize the time at which therapy for status epilepticus should be initiated. GCSE can be defined as at least five minutes of either continuous seizures or two or more discrete seizures between which there is incomplete consciousness recovery. This definition does not refer to a mechanism that defines the transition from an isolated seizure to status epilepticus. Recent experimental observations, however, indicate that potentially important molecular "switches" occur in neurotransmitter receptors within this general time frame and may have a critical role in causing the enhanced neuronal excitability that characterizes status epilepticus.

A comprehensive, community-based prospective study of status epilepticus from Richmond, Virginia, suggests that the frequency of cases of status epilepticus in the U.S. is approximately 100,000 to 150,000 per year, roughly twice as high as previously thought. This study has also verified a number of previous conclusions regarding the prime importance of etiology and age as determinants of outcome in status epilepticus. Patients with GCSE from etiologies having a chronic or remote basis (such as refractory epilepsy, discontinuation of antiepileptic drugs, or chronic ethanol abuse) generally respond well to treatment and recover. In contrast, patients with GCSE induced by more acute processes (such as metabolic abnormalities, infection, stroke, head trauma, or drug toxicity) often have seizures that are resistant to typical, front-line therapy and are associated with a substantially higher morbidity and mortality. Also, patients older than 60 are significantly more prone to complications related to GCSE.

Two recent advances have been made in the initial treatment of patients with GCSE. Intravenous lorazepam has supplanted intravenous diazepam as the most commonly used first-line drug therapy. Although lorazepam and diazepam have similar efficacy in aborting GCSE, the preference for lorazopam stems from the recognition that it has a significantly longer duration of antiseizure effect (12 to 24 hours for lorazepam compared to 15 to 30 minutes for diazepam). The other new aspect of initial therapy concerns the recent availability of fosphenytoin (Cerebyx). Fosphenytoin is a water-soluble pro-drug of phenytoin that is converted to phenytoin by nonspecific phosphatases. The water-solubility allows fosphenytoin to be combined with any intravenous fluid (as opposed to phenytoin, which precipitates when mixed with glucose-containing solutions). Fosphenytoin can also be infused faster (150 mg per minute of phenytoin equivalents) than phenytoin (50 mg per minute). The time to reach therapeutic serum levels of phenytoin is approximately the same for both drugs when using the suggested infusion rates. Theoretically, the lack of propylene glycol as a diluent for fosphenytoin suggests there should be fewer hypotensive or adverse cardiac effects compared to intravenous phenytoin. Other than a lower rate of infusion site reactions with fosphenytoin, however, no differences between the two drugs in frequency or scope of adverse events have been shown thus far.

Refractory status epilepticus refers to a situation in which patients do not respond to front-line therapy with lorazepam and phenytoin (or fosphenytoin) followed by loading doses of phenobarbital. Patients with refractory status epilepticus usually need to be managed in an intensive care unit, and they require careful neurological assessment, including regular monitoring with electroencephalography. Until recently, barbiturate coma was the preferred treatment for refractory status epilepticus, despite the recognition that this form of therapy was associated with a high frequency of complications, most notably hypotension. Intravenous midazolam and propofol have recently become popular alternatives to phenobarbital; these drugs appear to have a substantially lower incidence of complications.

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Drug Treatment for Alzheimer's Disease

ALZHEIMER'S disease (AD) can be diagnosed clinically and is a treatable disorder. Disease modifying and symptomatic therapies are available. Stage-specific treatment, control of behavioral disturbances, and care of the caregiver are all important aspects of therapy.

Treatment begins with the clinical diagnosis of AD and determination of its manifestations. In addition to an assessment of memory and other cognitive domains, a complete evaluation identifies associated behavioral disturbances, including delusions, dysphoria, apathy, irritability, anxiety, and disturbances in sleep or appetite. If the caregiver reports behavioral changes that urgently require treatment, the first arm of therapy consists of symptom-appropriate psychotropic medication.

The clinician must also determine the severity of AD. Therapies that slow its progression may be appropriate for earlier, but not later, phases of the disease. Similarly, symptomatic therapies are indicated for mild to moderate AD. In patients with advanced AD, cholinesterase inhibitors and neuroprotective agents prolong disability and caregiver burden instead of preserving function.

Recent studies have shown the benefits of neuroprotective agents such as vitamin E and selegiline. Vitamin E, 2000 IU once a day, and selegiline, 5 mg twice a day, each proved more effective than placebo therapy at both slowing the decline of cognition and functional ability and prolonging the time to death. Given together, the two drugs had neither an additive nor synergistic effect. Vitamin E has no side effects, which makes it a better choice for neuroprotective therapy.

Estrogen given to women as postmenopausal hormone replacement therapy may have a neuroprotective effect. Estrogen has already proven beneficial for depressed mood and mild memory impairment in patients, possibly through the preservation and promotion of dendritic synapses, antioxidant effects, cholinergic effects, and maintenance of vascular competency.

Donepezil is the current drug of choice for symptomatic treatment of AD. This cholinesterase inhibitor specifically targets the central nervous system and compensates for the cholinergic deficit present in the brain in AD. It offers a more benign side effect profile than its predecessor, tacrine. Donepezil is given once a day, can be increased to maximal dose (10 mg a day) after the first month at 5 mg a day, and spares patients frequent phlebotomy to assess liver functions. Donepezil and tacrine have equal efficacy. Some behavioral disturbances also may improve with donepezil treatment, and the clinician should track behavioral changes along with memory and ADL function at follow-up evaluations. Donepezil is coadministered with vitamin E and, in women, with estrogen replacement therapy. If behavior problems persist, psychotropic medication should be given as well.

There is no AD-specific treatment available or appropriate for the disease's late and end stages. In the absence of such treatment, the clinician bears the responsibility of giving stage-specific counsel to the patient and the caregiving family. Patients with advanced disease may still require psychotropic agents for the control of disturbing behavior, and these should be used as necessary. Attention to skin care, nutrition, and hydration are critical. The protocol for treatment will change drastically in the coming years, as muscarinic cholinergic agonists and new recommendations regarding neuroprotection with nonsteroidal anti-inflammatory agents, neurotrophins, and other agents become available.

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The Role of Apolipoprotein E Testing in the Diagnosis of Alzheimer's Disease

THE importance of early and accurate diagnosis of dementia has become increasingly recognized, particularly when associated with Alzheimer's disease (AD). A key reason for this is heightened public awareness of dementia: symptoms such as failing memory are likely to be brought to medical attention rather than dismissed as unimportant or due to aging.

Treatment strategies in AD that aim to slow clinical progression require early diagnosis supported by early treatment initiation. The standard method of diagnosing AD remains the clinical approach, in which the clinician obtains a history of cognitive decline, documents that recent memory and other areas of cognition are impaired, and rules out other causes of dementia. For early diagnosis, brief screening tests such as the Mini-Mental State Examination are insensitive. By expanding the tests of memory, abstraction, drawing, and language, the clinician can increase the diagnostic yield; for many patients, however, serial testing, over months and sometimes years, is necessary to document progressive cognitive decline. The clinical problems associated with the early detection and differential diagnosis of dementia have fueled studies of the role of biological markers (such as neuroimaging and the testing of cerebrospinal fluid and blood) and genetic (DNA) risk factors as diagnostic aids. The most consistent findings involve testing for variants of Apolipoprotein E (Apo-E).

Apo-E is a lipoprotein that is involved in cholesterol transport in the brain. Humans have three major genetic variants (alleles) of Apo-E—e2, e3, and e4. In the general population, e3 is the most common allele. According to numerous studies, the e4 allele carries an increased risk for the development of AD. A recent study that pooled data from many centers has clarified the extent of risk: overall, the e4/e4 genotype increased the risk of AD by 15-fold, while the e3/e4 and e2/e4 genotypes increased the risk about 3-fold (compared to the e3/e3 genotype). The effect of e4 was particularly evident for patients with dementia onset in their 60s and 70s. The e4 allele is estimated to be associated with about 40% to 50% of cases of sporadic AD.

How could Apo-E e4 fit into a diagnostic approach to dementia? Presymptomatic screening is unlikely to be useful because of the widely varying and unpredictable age at onset of AD among e4 bearers, the lack of protection from AD in e3/e3 bearers, and the lack of proven preventive therapy for AD. Apo-E genotyping in someone without cognitive decline provides only a vague prediction of the magnitude and timing of the risk of AD.

A stronger case can be made for using Apo-E in the clinical diagnosis of AD. Several autopsy studies have shown that the e4 allele is increased specifically in patients who showed pathology of AD, not of other brain disorders. This implies that in a demented subject, the presence of one or two e4 alleles makes AD more likely, and the absence of an e4 makes AD slightly less likely. In patients with dementia who do not have clear clinical diagnoses, or when more than one potential cause of dementia is present, Apo-E genotyping may increase the confidence that AD is present if one or two e4 alleles are found.

By extension, Apo-E genotyping may have some value in early diagnosis. In an older patient with mild memory dysfunction, the presence of the Apo-E e4 allele increases the likelihood that the symptoms are AD-related (rather than associated with normal aging or depression). The absence of an e4 allele, however, only marginally decreases the likelihood of AD. In studies of older people with mild memory difficulty or with risk factors for AD, Apo-E genotyping has been shown to be a predictor in those whose symptoms progress to clinically diagnosed AD. In short, the main value of Apo-E as an adjunct to diagnosis comes when AD cannot be confidently excluded and other conditions fall into the equation. Finding one or more e4 alleles can then alert clinicians to the probability of AD. As is the case with diagnostic tests in general, good clinical judgment is essential to maximize the value and interpretability of Apo-E genotyping in relation to dementia.

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Genetic Testing

RECENT advances in molecular biology have resulted in a rapidly expanding number of diagnostic tests for neurogenetic disorders. Gene discovery has led to direct DNA tests for disease-causing mutations. Many of these tests are based on trinucleotide repeat expansions underlying at least 11 different disorders. Eight are autosomal dominant, including Huntington's disease, myotonic muscular dystrophy, and several types of spinocerebellar ataxias (SCA); two are X-linked including fragile X mental retardation and Kennedy's spinal bulbar muscular atrophy (SBMA); and one is autosomal recessive (Friedreich's ataxia). Other commercially available DNA tests for point mutations, duplications, or deletions include one type of familial amyotrophic lateral sclerosis (ALS) (superoxide dismutase 1); one form of early-onset familial Alzheimer's disease (presenilin 1); and three types of hereditary neuropathy (Charcot-Marie-Tooth Type 1A [CMT1A], X-linked Charcot-Marie-Tooth [CMTX], and hereditary neuropathy with liability to pressure palsies [HNPP]). Several tests are also available for the common mutations that occur in mitochondrial DNA including MELAS (mitochondrial encephalomyopathy with lactic acidosis and stroke), MERRF (myoclonic epilepsy with ragged red fibers), and LHON (Leber's hereditary optic neuropathy).

These DNA tests have advantages and disadvantages. The greatest advantage is that they are highly specific and are remarkably valuable diagnostic tools. They are often considered the gold standard of diagnosis. A positive test establishes an exact diagnosis, whereas a negative test encourages further evaluation for other causes of the clinical syndrome. The results are also important for accurate genetic counseling, because a positive result indicates the pattern of inheritance. (For example, CMT1A and familial ALS are clinically similar to CMTX and Kennedy's SBMA, respectively, but the first two disorders are autosomal dominant and the second two are X-linked.) There is sometimes an economic advantage; for instance, a single DNA test may be much less expensive than an extensive but less specific battery of clinical tests. Also, DNA tests may lead to an early identification of gene carriers that will make them available for early therapeutic intervention.

DNA testing also carries many potential disadvantages. A positive DNA test for a serious neurogenetic disorder such as Huntington's disease may lead to tremendous anxiety and depression in some patients. Therefore, DNA testing of asymptomatic family members at risk for the mutation should be done in the context of formal genetic counseling. There is concern that DNA testing may create persons who are "genetic outcasts," who will be unable to obtain insurance or employment. It is unclear how the results of DNA testing should be used in legal proceedings such as divorce, child custody, or criminal prosecution. Families may have exaggerated expectations from DNA testing, so it is important to note that most positive tests do not provide useful information regarding age of onset or type or severity of clinical symptoms.

The testing of children is also controversial. There is concern that asymptomatic children with known genetic mutations may be raised "differently" (so-called self-fulfilling prophecy). Most centers delay DNA testing of children until they reach adulthood and can make the testing decision for themselves. An exception to this rule would be the testing of children who have symptoms of the disease and would benefit from an accurate diagnosis.

Many genetic disorders may be caused by different mutations at the same site on a chromosome. A DNA test for only a specific mutation may therefore be negative, even though the patient clinically has signs of the disease. The most vivid example of this is Duchenne type muscular dystrophy, in which there are over 50 different genetic variants of abnormalities in the dystrophin gene that all phenotypically present as Duchenne's; as many as 30% of these patients have a negative DNA test. DNA testing in prenatal diagnosis is also complex and involves many of the same legal and ethical issues that surround abortion.

It is difficult for the busy clinician to know which genetic tests are commercially available. A website exists to provide up-to-date information on the availability of both commercial and research genetic tests (http://healthlinks.washington.edu/helix). Another website, http://www.ncbi.nlm.nih.gov, has clinical information regarding the Human Genome Project and an online version of Victor McKusick's textbook, *Mendelian Inheritance in Man;* it is frequently updated as new information about genetic disorders is published.

DNA testing for neurogenetic diseases is a powerful and valuable diagnostic tool that should be used judiciously on an individual basis. The decision to proceed with such testing should be made only after considering all of the potential risks and benefits.

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Issues for Women with Epilepsy

EPILEPSY is a neurological disorder affecting 1% or more of the population. While the incidence of epilepsy is not significantly different between men and women, epilepsy raises special concerns and challenges for women. Female physiology alters the expression of seizures and may influence medication efficacy. Seizures and antiepileptic drugs (AEDs) alter hormones of the hypothalamus, pituitary, and gonads and may affect reproduction. Pregnant women with epilepsy risk more frequent seizures, pregnancy complications, and AED-related birth defects.

Many hormones influence brain electrical excitability, including gonadal and adrenal steroids and thyroid hormone. Estrogen has a seizure activating affect in experimental models and in humans, whereas progesterone has a seizure-protective effect. These neuroactive steroids alter the synthesis of the inhibitory neurotransmitter GABA and of the $GABA_A$ receptor, and they also alter activity at membrane receptors for GABA and for the excitatory neurotransmitter, glutamate. Approximately 30% of women with epilepsy report catamenial (menstrual associated) seizure patterns, with seizures more likely to occur in the perimenstrual period. Little information is available regarding changes in epilepsy at menopause or with postmenopausal hormone replacement therapy.

AEDs that alter the hepatic cytochrome P450 (cyP450) enzyme system are associated with changes in the metabolism and protein-binding of endogenous and contraceptive steroid hormones. Medications that induce cyP450 enzymes and reduce steroid hormone concentrations include phenytoin, carbamazepine, barbiturates, and topiramate. Women on these AEDs experience a failure of oral hormonal contraceptives of 6% or more per year. The risk is highest with hormonal contraceptives containing low doses of estrogen (35 μg or less). The failure risk at higher hormone doses (50 μg of estrogen) is not known, although the risk theoretically should be less. Drugs that inhibit or have no effect on the cyP450 enzyme system do not compromise hormonal contraception. Felbamate and valproate inhibit the cyP450 enzymes and gabapentin; lamotrigine and vigabatrin have no effect. For women on cyP450-inducing AEDs, barrier methods of contraception should be considered.

Reproductive function may be adversely impacted in women with epilepsy. Fertility rates in women with epilepsy are one-third those of nonepileptic siblings. Women with epilepsy have a higher frequency of anovulatory menstrual cycles, abnormal menstrual cycle length, and polycystic ovaries than do nonepileptic women. Reproductive endocrine disorders described in women with epilepsy include abnormalities in basal and pulsatile luteinizing hormone secretion, elevations in pituitary prolactin, and disturbances in gonadal steroids. These alterations in reproductive hormones occur both in women treated and in women not treated with AEDs. Until the mechanisms of reproductive dysfunction in women with epilepsy are delineated, symptomatic women should be referred for gynecologic evaluation.

Women with epilepsy are also at risk for sexual dysfunction. More than one-third of women with epilepsy experience disorders of sexual arousal. These manifest clinically as complaints of dyspareunia, vaginismus, and arousal insufficiency. Sexual desire may also be adversely affected. There are several etiologies to account for the sexual dysfunction in epilepsy. Seizures can restrict opportunities for forming and maintaining intimate relationships. Epileptic discharges can disrupt the function of brain structures mediating sexual behavior, such as the limbic cortex, and can disturb hypothalamic and pituitary hormone release. AEDs change levels of pituitary and gonadal hormones involved in sexual behavior by altering metabolism and protein binding and probably also through direct effects on the hypothalamic-pituitary axis. Women with sexual dysfunction should undergo an endocrine evaluation (thyroid hormones, estrogen, testosterone, and prolactin), psychological evaluation, and referral to a gynecologist. Changing to another AED is sometimes helpful.

Pregnancy raises several concerns for woman with epilepsy, including the risk of more frequent maternal seizures, of pregnancy complications, and of birth defects. Fortunately, a better understanding of the risks associated with pregnancy in the epileptic patient has led to treatment strategies to optimize outcome.

About 25% to 30% of women with epilepsy have more frequent seizures during pregnancy, while a similar number find that seizures are less frequent. Poor seizure control may be related to lower total levels of AED. To a lesser extent, the non-protein bound fraction of AED may be decreased as well. Women with epilepsy also have more pregnancy complications such as vaginal bleeding and abruptio placentae, and there is a two-fold increase in the incidence of adverse pregnancy outcomes, including fetal wastage and neonatal and perinatal death.

AED use during pregnancy is associated with a higher risk of fetal malformation. The risk of congenital malformation, such as cleft lip or palate and ventricular septal defect, is 4% to 8% in infants of mothers with epilepsy who are exposed to any AED, compared to 2% to 4% of infants born to women without epilepsy. There is a 1% to 2% incidence of neural tube defects in fetuses exposed to valproic acid during the first trimester, and a 0.5% to 1%

risk after exposure to carbamazepine. Congenital anomalies, mostly involving the mid-face and digits, occur in between 5% to 30% of infants exposed to AEDs. AED-associated teratogenesis may occur because of fetal exposure to toxic free-radical AED intermediates. Particularly susceptible people are those with deficiencies in free-radical metabolizing enzymes. Malformations may also occur as a result of AED-related folate deficiency.

Specific treatment strategies can significantly reduce these risks. Treatment with folate before conception and during pregnancy substantially reduces the risk of neural tube defects in nonepileptic women who are at risk and is thought to confer the same protective action in women with epilepsy. The optimal dose is not established but appears to be between 0.4 mg and 4 mg per day. Indicated prenatal diagnostic testing for women with epilepsy includes high resolution ultrasound and maternal serum alpha-fetoprotein obtained between 16 and 18 weeks gestation; neural tube defects will be detected with greater than 95% sensitivity. Vitamin K is administered during the final month of pregnancy as oral Vitamin K1 (phytonadione, 10 mg per day) to prevent AED-associated fetal and maternal coagulopathy. Adverse outcomes are minimized by treating with AED monotherapy, rather than polytherapy, and by using the lowest effective AED dose. Monitoring the non-protein bound fraction of AED is most accurate during gestation.

The new AEDS (felbamate, gabapentin, lamotrigine, tiagabine, topiramate) have limited human pregnancy experience, but these drugs have not been teratogenic in animals. A prospective AED pregnancy registry has been established by an independent scientific advisory group and financed by five pharmaceutical companies manufacturing AEDs. Women who become pregnant while receiving any AED should be encouraged to enroll with the registry (contact information is provided below).

Epilepsy is a chronic illness that affects women during the child-bearing years. The expression of epilepsy may be altered with physiological changes in ovarian steroid hormones and as a consequence of exposure to therapeutic steroid hormones. Fertility may be reduced because of alterations in the hypothalamic pituitary-gonadal axis, in gonadal steroid concentrations, and in ovarian morphology. Sexual dysfunction may present as specific physiological complaints. Pregnancy and fetal outcome can be maximized by maintaining seizure control, utilizing AED monotherapy, and reducing peak-dose exposure. Routine folic acid supplementation appears prudent for any woman of child-bearing potential on AEDs. Further information is available for health care professionals and consumers through the Epilepsy Foundation.

The Antiepileptic Drug Pregnancy Registry
Genetics and Teratology Unit
14CNY-MGH East
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Charlestown, MA 02129-2000
1-888-233-2334
website: neuro-www2.mgh.harvard.edu/aed/registry.nclk
Epilepsy Foundation
4351 Garden City Drive
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New Pharmacological and Surgical Therapies for Parkinson's Disease

REPLACEMENT therapy with dopamine precursors (levodopa) or dopamine agonists remains the mainstay of symptomatic therapy for Parkinson's disease. Two new selective dopamine D-2 and D-3 receptor agonists, pramipexole and ropinirole, are now available. Both are being used as initial treatment for symptomatic Parkinson's disease and can delay the need for levodopa by one or more years. As monotherapy, pramipexole and ropinirole are largely devoid of the adverse effects that frequently complicate treatment with levodopa, namely motor fluctuations (in the most severe form known as "on-off") and dyskinesia (involuntary choreic movements). Pramipexole and ropinirole are also used with levodopa in more advanced patients to prolong the response to each dose of levodopa and to reduce the trough severity of parkinsonism. Both new agonists are well tolerated but can have adverse effects that resemble those of other dopaminergic agents, such as nausea, dizziness, orthostatic hypotension, confusion, and hallucinations. In conjunction with levodopa, they can cause dyskinesia. Because pramipexole and ropinirole are not ergot derivatives, they may lack rare adverse effects such as retroperitoneal and pulmonary fibrosis associated with the older dopamine agonists. Direct comparisons among the new and old dopamine agonists are scant, but some studies suggest that ropinirole and pramipexole may be superior to bromocriptine.

Tolcapone and entacapone, inhibitors of catechol-O-methyl transferase (COMT), will be introduced in the near future; Tolcapone is FDA approved. These drugs block O-methylation of levodopa to an inert compound, thereby slowing clearance of levodopa from plasma and increasing the amount of levodopa entering the brain, which enhances the response to levodopa. Their effect is somewhat like controlled-release levodopa. The COMT inhibitors have no clinical effect unless they are combined with levodopa. The side effects of tolcapone and entacapone alone are diarrhea. In combination with levodopa, the adverse effects are the same as those of excessive levodopa, so it is often necessary to reduce the levodopa dose.

Protective therapies to slow the degeneration of dopaminergic neurons remain at the forefront of scientists' and clinicians' minds. Selegiline, a selective, irreversible MAO-B inhibitor, was widely adopted following the Parkinson's Study Group report that it delayed the need to start levodopa by over a year. The initial enthusiasm for selegiline has been tempered by the recognition that selegiline can reduce or reverse symptoms but not necessarily affect the progression of the disease. So although selegiline's symptomatic actions can contribute to the delay in need for levodopa, it does not clearly alter progression of the disease once levodopa is started. A large British study suggested that selegiline increased mortality rates, but this finding has not been replicated. Thus, the protective actions of selegiline are controversial. In current clinical practice, selegiline is more commonly used in patients early in the disease and withdrawn later in the course when patients are on multiple antiparkinsonian drugs. It can cause confusion, dyskinesia, orthostatic hypotension, and nausea. Despite the uncertainties that surround selegiline, the search for protective therapies continues with investigations of agents to reduce free-radical formation and damage in the basal ganglia, of glutamate antagonists to reduce excitotoxicity, and of mitochondrial electron chain cofactors to enhance neuronal energy production.

Thalamotomy is increasingly used for disabling rest or postural tremor that is unresponsive to pharmacological management. Unilateral thalamotomies abolish or greatly reduce contralateral tremor but do not affect the other parkinsonian signs of rigidity and bradykinesia. Bilateral procedures are associated with a high incidence of dysarthria, dysphagia, and disequilibrium, and they are only reluctantly used in severely affected patients. A new approach is to implant stimulating electrodes in the thalamus, because high-frequency stimulation will inactivate neurons in the vicinity of the electrode tip and produce a reversible thalamotomy. Adverse effects can be minimized by altering the stimulation parameters, and bilateral procedures can be done without the concern of irreversible dysarthria, dysphagia, and disequilibrium. The drawbacks are the expense of the stimulator, the periodic need for battery replacement, and the considerable effort required to find the optimal stimulation parameters. A common compromise is to do a thalamotomy on the first side and, if needed, thalamic stimulation on the contralateral side at a later date. Pallidotomy ameliorates contralateral levodopa-induced dyskinesia. It may also improve other aspects of parkinsonism, but severe dyskinesia is the major indication for the procedure. The adverse effects of bilateral pallidotomies are similar to those of bilateral thalamotomies and are therefore rarely performed. Unilateral and bilateral stimulation of the pallidum and subthalamic nucleus are promising, safer techniques that are under intense investigation for treatment of parkinsonism.

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Recent Advances in the Treatment of Neuropathies

THERE is a growing arsenal of immunomodulating therapies—including glucocorticoids, immunosuppressant drugs, intravenous immune globulin (IVIg), and plasmapheresis—that is used to treat peripheral neuropathies. These therapies control underlying immune processes that attack nerves. Recovery from dysimmune neuropathies, however, requires more than the control of underlying immune processes. It also requires repair and recovery of the peripheral nerve that no therapy has been shown to enhance or alter. In axonal neuropathies, the goal is stabilization of function, because recovery follows axon regeneration and collateral reinnervation. This takes years and is incomplete. In demyelinating neuropathies, the goal is restoration of function, because recovery follows remyelination. This takes only months and is complete. Once full benefit is achieved, whether stabilization or restoration, therapy should be reduced—it is toxic or costly. Therapy reduction requires close surveillance for clinical relapse, which would indicate that control over underlying immune processes attacking the nerve has been lost.

Over a decade ago, French and North American studies demonstrated that acute idiopathic demyelinating neuropathy, Guillain Barré syndrome (GBS), can be treated with plasmapheresis. A recent follow-up study found doses can be adjusted to severity without losing benefit: two plasma exchanges in mild GBS and no more than four plasma exchanges in moderate and severe GBS. The Dutch have found that IVIg is as effective as plasmapheresis. Plasmapheresis requires special equipment available at special centers, whereas IVIg is widely available. Plasmapheresis may cause hypotension and malaise; IVIg causes fever, headache, myalgia, rash, anaphylactic reaction, thromboses, infarcts, congestive heart failure, and hepatitis C. The frequency of side effects is similar between the treatments. Both cost about $6,000 to $12,000 for four to six treatments. The cost is not trivial, but it is justified by the savings that comes from reduced hospitalization, morbidity, and disability.

Traditionally, chronic idiopathic demyelinating neuropathy has been treated with large glucocorticoid doses (prednisone, 1 to 2 mg per kg of body weight a day, up to 100 mg a day). There is a growing tendency to use other immunomodulatory therapies alone or in various combinations as alternatives or as adjuncts to glucocorticoids. Plasmapheresis and IVIg are effective in controlling disease. Maintenance therapy every four to six weeks is usually necessary. Azathiaprine, cyclophosphamide (in oral daily doses or monthly intravenous pulses), and cyclosporin A are increasingly used as adjunct, steroid-sparing therapy, as alternatives to glucocorticoid therapy, or as second-line therapy. Eradication rather than mere control of disease is achievable in some patients. No well-conducted trial has compared these therapies directly. Drug therapy takes months before seeing its benefit, so combining modalities is sensible. Therapy is often started with plasmapheresis or IVIg for early reversal of deficits and maintained with drugs for long-term control (if not eradication).

Multifocal motor neuropathy may represent a variant of chronic idiopathic demyelinating polyneuropathy. It starts with progressive, asymmetric, pure, or mostly pure motor weakness, atrophy, and fasciculations and resembles motor neuron disease, for which it is occasionally tragically mistaken. It is caused by immune-mediated focal demyelination in peripheral nerves, which leads to conduction blocks. An association with antibody to GM1 ganglioside, initially believed to be hallmark, is now known to be inexact—probably only 50% of patients have the antibody. Treatment is usually gratifying with IVIg; most patients depend on treatment every four to six weeks. If treatments begin to fail, either dose or frequency of IVIg may be increased or other immunomodulating therapies, especially cyclophos phamide, may be invoked.

The association between neuropathy and paraproteinemia has been appreciated for over a decade. Ten percent of patients with neuropathy have a monoclonal gammopathy (as opposed to 0.1% to 3.0% of the general population) and nearly 50% of gammopathy patients have neuropathy. But despite intense interest, the correlation of clinical syndrome and paraproteinemic syndrome remains unclear. Antibodies to various peripheral nerve antigens including myelin associated glycoprotein (MAG), sulfatide, GMT, asialo-GM1, and GD1b can be detected, but doing so has dubious value for classifying the neuropathy and determining the course of therapy. Therefore, these determinations have a limited role. Therapy should be directed at the cause of the paraproteinemic syndrome, such as myeloma, plasmacytoma, lymphoma, or amyloidosis. If the cause of the paraproteinemia is established, so-called monoclonal gammopathy of undetermined significance, therapy of the neuropathy should depend on clinical circumstances and pathophysiolgy. Immunomodulating therapy should be used for demyelinating neuropathies; cautious (if any) therapy should be used for axonal neuropathies because treatment may be ineffective and hazardous and have a benefit that is difficult to monitor.

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Endovascular Treatment of Vasospasm

CEREBRAL vasospasm is a serious complication facing patients with aneurysmal subarachnoid hemorrhage (SAM) and is the leading cause of death and disability in this group. Because vasospasm is a delayed phenomenon, its occurance can lead to a poor outcome despite a technically successful early aneurysm clipping. Identifying vasospasm is based on symptoms, with confirmation by diagnostic testing. Transcranial Doppler (TCD) is a bedside, noninvasive technique, but it suffers from problems with sensitivity and specificity, operator dependence, and inconsistent visualization. Cerebral angiography, the gold standard for the detection of vasospasm, is invasive and carries a small, but real, risk of vessel injury, stroke, or death.

The traditional treatment of vasospasm includes intravascular volume loading, maintenance of hypertensive blood pressure, and administration of calcium channel blockers. Recently, endovascular technology has been adapted as an adjunct therapy. Using standard transfemoral cerebral angiography access, newer generation guidewires and catheters allow superselective catheterization of intracranial vessels, including navigation of vessels at the circle of Willis and beyond. By selective placement of a catheter, focal therapy can be delivered at the location of maximal spasm.

Papaverine, an agent that relaxes arterial beds by directly inhibiting smooth muscle, can be infused via a microcatheter into a spastic cerebral bed. The appeal of this approach is localized delivery, which minimizes systemic hypotensive effects. In addition, because papaverine will exhibit some therapeutic effect downstream to the point of release, it is not necessary to place the catheter tip at the target site. This feature may be useful when it is technically impossible to place the catheter precisely because of unfavorable anatomy or when rapid completion of the procedure is necessary because of the patient's condition. About two-thirds of spastic vessels will respond to papaverine infusion. Spasm resolution typically occurs within minutes but may require up to 90 minutes before an effect is demonstrable. It is important to note that clinical improvement does not necessarily correlate with angiographic resolution of spasm. Furthermore, successful papaverine treatment does not afford durable protection against future development of spasm. Our experience is that the duration of effect is less than 24 hours; retreatment may be necessary within that interval. The mechanisms underlying papaverine's variable effects are obscure but may involve differential sensitivity as a vessel progresses through phases of spasm.

Transluminal angioplasty offers a mechanical technique for dilating spastic segments. In one series, 15 out of 18 spastic vessels responded favorably, accompanied by clinical improvement in four out of five patients. Unlike papaverine, the angioplastic balloon must be delivered precisely to the spastic site. This may not always be possible due to technical limitations related to guidewire and catheter designs. Sites typically accessible include the distal internal carotid, the M1 segment of the middle cerebral artery, and the vertebral and basilar arteries. The A1 segments of the anterior cerebral and the P1 segments of the posterior cerebral arteries are less consistently navigable. Therefore, angioplasty is currently best suited for treating focal narrowing in accessible locations.

A potential risk of either papaverine or angioplasty is the vasodilation of an injured, incompetent vascular bed and subsequent hemorrhagic conversion of a preexisting bland infarct. While rare, the consequences of such a reperfusion hemorrhage can be disastrous. Because of this possibility, we recommend obtaining a noncontrast computed tomographic (CT) scan of the head before beginning endovascular treatment. The presence of significant areas of hypodensity within the target vascular distribution probably represents a contraindication to papaverine or angioplasty. Other reported complications with papaverine include transient or permanent neurologic deficits, paradoxic exacerbation of vasospasm, and systemic effects such as thrombocytopenia and heart block. Potential complications of angioplasty include intimal injury, vessel rupture, dislodgement of aneurysm clips, and distal embolization from disrupted plaque. In the setting of an unsecured aneurysm, one theoretical risk is that angioplasty or papaverine therapy could produce a sudden increase in the downstream pressure-head of blood, which could lead to aneurysmal rupture.

Neither papaverine nor angioplasty stands alone as comprehensive vasospasm therapy, and each requires careful integration into the overall care of the patient with SAH. In the patient with clinical and TCD evidence of vasospasm, we believe that cerebral angiography should only be performed if the patient is a candidate for endovascular therapy. Before angiography, the patient needs a noncontrast CT of the head. If no contraindications exist, the patient should proceed to angiography with the intent of endovascular therapy by angioplasty, papaverine, or both. Papaverine and angioplasty are powerful, direct methods for ameliorating vasospasm in properly selected patients.

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EDITOR'S NOTE

This epitome was omitted from the Neurosurgery epitomes feature in the June 1997 issue of the WESTERN JOURNAL OF MEDICINE. As a topic related to neurology, it is included in this issue.

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Advice for Travelers

Patients planning to travel to other countries often ask physicians for advice about immunizations and prevention of diarrhea and malaria. Legal requirements for entry and epidemiological conditions in different countries vary from time to time, often unpredictably, but some reasonable recommendations can be made. More detailed information is available in *Health Information for International Travel,* published biannually by the Centers for Disease Control and Prevention (CDC), which can be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202-512-1800). Up-to-date automated information is available from the CDC at 888-232-3228 or on the internet at www.cdc.gov.

TRAVELERS' DIARRHEA—The most common cause of travelers' diarrhea, usually a self-limited illness lasting several days, is infection with enterotoxigenic *E. coli. Campylobacter, Shigella, Salmonella,* viruses, and parasites are less common causes of this disorder. Travelers to areas where hygiene is poor should be advised to avoid foods that are not steaming hot, raw vegetables, fruit they have not peeled themselves, and tap water, including ice.

Prophylaxis—*Medical Letter* consultants generally do not prescribe drugs prophylactically, but rather instruct the patient to begin treatment promptly when symptoms occur. When prophylaxis is used, ciprofloxacin *(Cipro)* 500 mg once daily, levofloxacin *(Levaquin)* 500 mg once daily, ofloxacin *(Floxin)* 300 mg once daily, or norfloxacin *(Noroxin)* 400 mg once daily is recommended for a maximum of three weeks. Bismuth subsalicylate *(Pepto-Bismol,* and others) can also prevent diarrhea in travelers who take two tablets four times daily, but it is less effective than antibiotics.

Treatment—Loperamide hydrochloride *(Imodium,* and others), an over-the-counter synthetic opioid (for adults a 4-mg loading dose, then 2 mg orally after each loose stool, to a maximum of 16 mg per day), plus a single dose of ciprofloxacin (750 mg), levofloxacin (500 mg), or ofloxacin (400 mg) usually relieves the symptoms of traveler's diarrhea in less than 24 hours (CD Ericsson et al, *J Travel Med* 1997; 4:3). If diarrhea is severe or associated with high fever or bloody stools, ciprofloxacin (500 mg b.i.d.), levofloxacin (500 mg once daily), norfloxacin (400 mg b.i.d.), or ofloxacin (300 mg b.i.d.) for three days is recommended for adults. Trimethoprim-sulfamethoxazole *(Bactrim,* and others) can be used for children, but resistance to it has become common in many areas.

IMMUNIZATION—Cholera—The risk of cholera to tourists is very low; the parenteral vaccine currently licensed in the U.S.A. has limited effectiveness, often causes reactions, and is not recommended for travelers. Two new oral vaccines are available in some other countries. Neither is recommended for routine use in travelers.

Hepatitis A—Hepatitis A vaccine *(Havrix*—SmithKline Beecham; *VAQTA*—Merck) is recommended for susceptible travelers going anywhere outside the U.S.A., Canada, Western Europe, Japan, Australia, or New Zealand (*Medical Letter* 1995; 37:51). The *Havrix* vaccine is given as a single dose to adults (1 mL = 1440 ELISA units) and children two to 18 years old (0.5 mL = 720 ELISA units), followed by a booster dose six to 12 months later. The *VAQTA* vaccine is given as a single 1-mL dose for adults (~ 50 units) and a 0.5-mL dose for children two to 17 years old (~25 units), followed by a booster dose six to 18 months later. Protective levels of antibodies are detectable in adults two to four weeks after the first dose.

Hepatitis B—Vaccination against hepatitis B *(Recombivax HB*—Merck; *Engerix B*—SmithKline Beecham) is not ordinarily recommended for foreign travel, except for high-risk travelers or those who may require medical or dental care in areas where hepatitis B is highly endemic (*Medical Letter* 1992; 34:69). Such areas include China, Southeast Asia, most of Africa, most of the Middle East, the South Pacific, the Amazon region in South America, Haiti, and the Dominican Republic. Travelers at high risk include health-care workers, those planning a long stay in an endemic area, and anyone who might have sexual contact with new partners or prostitutes. Primary immunization consists of three doses given IM in the deltoid (the anterolateral thigh in neonates and infants) on a schedule of 0, 1 to 4, and 6 to 18 months. An accelerated schedule of three doses given at 0, 1, and 2 months, with a fourth dose given 12 months after the first dose, can be used with *Engerix-B.*

Japanese encephalitis—Vaccination against Japanese encephalitis, a frequently fatal mosquito-borne viral disease that occurs in rural Asia, should be considered for travelers who anticipate more than 30 days' stay in rice-growing areas where they will be heavily exposed to mosquitoes, particularly in the rainy season. The attack rate in travelers is very low; in the past 10 years, fewer than 10 cases, most of them in military personnel, have been documented in U.S. citizens. A formalin-inactivated, purified, mouse-brain-derived vaccine that has been shown to protect against the disease is available in the U.S.A. for travelers at least one year old *(JE-Vax*—Pasteur Merieux

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Connaught). Allergic reactions including urticaria and angioedema occur in 0.5% of vaccinees, and may not begin until 24 to 72 hours, or as long as 10 days, after vaccination. Because of this high rate of vaccine-associated adverse events, vaccination is recommended only for travelers at high risk. When indicated, a primary series of three doses, given over two to (preferably) four weeks, is recommended. A booster dose can be given three years later.

Measles—People born after 1956 who have not received two doses of measles vaccine (after their first birthday) and do not have a physician-documented history of infection or laboratory evidence of immunity should receive a single dose of measles or measles-mumps-rubella vaccine before traveling.

Meningococcal disease—Meningococcal vaccine is recommended for tourists traveling to areas where epidemics are occurring. Epidemics occur frequently in sub-Saharan Africa from December to June, and also in northern India and Nepal. Saudi Arabia requires a certificate of immunization for pilgrims to Mecca or Medina. A quadrivalent single-dose meningococcal polysaccharide vaccine against *Neisseria meningitidis* serogroups A, C, Y, and W135 *(Menomune)* is available from Pasteur Merieux Connaught. The duration of immunity is about three years.

Polio—Adult travelers to tropical or developing countries outside the Western Hemisphere who have not previously been immunized against polio should receive a primary series of enhanced inactivated polio vaccine (eIPV). Previously unimmunized children should receive a primary series of eIPV or trivalent (live) oral polio vaccine (OPV). Travelers who have previously completed a primary series and have never had a booster should receive a booster dose of eIPV or OPV. If protection is needed within four weeks, a single dose of eIPV or OPV is recommended, but OPV rarely can cause vaccine-induced polio, particularly in previously unimmunized adults.

Rabies—Pre-exposure immunization against rabies is recommended for travelers with an occupational risk of exposure, for those, especially children, planning extended stays in endemic areas, and for outdoor-adventure travelers going to rural destinations in endemic areas. Three vaccine preparations are now available in the United States: Human Diploid Cell Vaccine (HDCV; *Imovax*—Pasteur Merieux Connaught), Rabies Vaccine Adsorbed (RVA—SmithKline Beecham), and the newly approved Purified Chick Embryo Cell Vaccine (PCEC; *Ra-bAvert*—Chiron). The standard pre-exposure immunization schedule for HDCV, RVA, and PCEC consists of a series of three doses given as intramuscular injections in the deltoid area, one each on days 0, 7, and 21 or 28. Alternatively, HDCV (only) can be given intradermally. Antimalarial drugs may interfere with the antibody response to rabies vaccines, especially when the vaccine is given intradermally.

Tetanus and Diphtheria—Whether traveling or not, everyone who has had a primary series as a child should receive a tetanus-diphtheria toxoid (Td) booster injection once every 10 years. For travelers, a Td booster is recommended especially for those going to developing countries and to Russia and Ukraine, where a large outbreak of diphtheria has been occurring in recent years.

Typhoid—Typhoid vaccine is recommended for travelers going outside usual tourist routes in countries where typhoid tends to be endemic, such as some areas of Latin America and Asia, or to any area where an outbreak is occurring. A live-attenuated oral vaccine *(Vivotif)* available in the U.S.A. from Berna Products (800-533-5899) and a purified capsular polysaccharide single-dose parenteral vaccine *(Typhim Vi*—Pasteur Merieux Connaught) have supplanted the older parenteral vaccine prepared from killed bacteria. The newer vaccines offer comparable levels of protection (50% to 80% effectiveness) with less toxicity. The oral vaccine, recommended for adults and children at least six years old, is taken as a single capsule without food every other day for a total of four capsules, beginning at least two weeks before departure. Antibiotics should be avoided around the time of administration. The *Typhim Vi* purified capsular polysaccharide vaccine for adults and children at least two years old is given as a single intramuscular dose at least two weeks before departure.

Yellow Fever—Yellow fever vaccine, an attenuated live virus vaccine prepared in eggs, is recommended 10 days before travel to areas in the yellow fever endemic zones, which include most of tropical South America and most of Africa between 15°N and 15°S. The vaccine is available in the U.S.A. only in centers designated by state health departments. Boosters are given every 10 years. Some countries in Africa require a certificate of yellow fever vaccination from all entering travelers; other countries in Africa, South America, and Asia require evidence of vaccination from travelers coming from or traveling through endemic or infected areas. Yellow fever vaccine should be avoided if possible in infants less than nine months old, and is contraindicated for infants under four months of age because of the risk of vaccine-induced encephalitis.

Other Considerations—More than one vaccine can be given at the same time. Immunocompromised or pregnant patients generally should not receive live virus vaccines.

MALARIA—Countries with a risk of malaria are listed in the table that follows; additional information is available from the Malaria Branch of the CDC at 770-488-

7788. Some countries with both urban and rural malaria may not have any malaria in major cities most frequently visited by tourists. Recommendations for malaria prophylaxis in adults and children were published recently in the *Medical Letter* (volume 40, page 6, Jan 2, 1998). Mefloquine *(Lariam)* 250 mg once a week is the drug of choice for adults traveling to areas with chloroquine-resistant malaria, except the Thai-Cambodian and Thai-Myanmar border areas and western Cambodia, where mefloquine resistance is common and doxycycline, 100 mg daily, is preferred. Chloroquine resistance has been reported in all areas where malaria occurs, except for Central America west of the Panama Canal Zone, Mexico, Haiti, the Dominican Republic, and most of the Middle East (chloroquine resistance has been reported in Iran, Yemen, Oman, and recently in Saudia Arabia). Contraindications to use of mefloquine for prophylaxis are a history of serious psychiatric illness, epilepsy, or a serious cardiac arrhythmia. Chloroquine *(Aralen,* and others) 300 mg base once a week is the drug of choice in areas with chloroquine-sensitive malaria. Travelers to countries with malaria should seek prompt medical attention for febrile illness while traveling or for up to three years after return.

COUNTRIES WITH A RISK OF MALARIA*

AFRICA

- Angola
- Benin
- Botswana
- Burkina Faso
- Burudi
- Cameroon
- Central African Republic
- Chad
- Comoros
- Congo
- Cote d’lvoire
- Democratic Republic of the Congo (formerly Zaire)
- Djibouti
- **Egypt
- Equatorial Guinea
- Eritrea
- Ethiopia
- Gabon
- Gambia
- Ghana
- Guinea
- Guinea-Bissau
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mauritania
- **Mauritius
- Mayotte (French territorial collectivity)
- Mozambique
- Namibia
- Niger
- Nigeria
- Rwanda
- Sao Tome and Principe
- Senegal
- Sierra Leone
- Somalia
- **South Africa
- Sudan
- Swazliand:
- Tanzania, United Republic of.
- Togo
- Uganda
- Zambia
- Zimbabwe

AMERICAS

- **Argentina
- **Belize
- **Bolivia
- Brazil
- **Colombia
- **Costa Rica
- **Dominican Republic
- Ecuador
- **EI Salvador
- French Guiana
- **Guatemala
- **Guyana
- Haiti
- **Honduras
- **Mexico
- Nicaragua
- **Panama
- **Paraguay
- **Peru
- **Suriname
- **Venezuela

ASIA

- Afghanistan
- Azerbaijan
- Bangladesh
- **Bhutan
- Cambodia
- **China, People’s Republic
- India
- Indonesia
- **Iran
- Iraq
- Lao People’s Democratic Republic
- **Malaysia
- **Myanmar
- **Nepal
- Oman
- Pakistan
- **Philippines
- Saudi Arabia
- **Sri Lanka
- **Syrian Arab Republic
- Tajikistan
- **Thailand
- Turkey
- United Arab Emirates
- **Viet Nam
- Yemen

OCEANIA

- Papua New Guinea
- Solomon Islands
- Vanuatu

*Adapted from *Health Information for International Travel,* 1996-1997. Only includes countries for which prophylaxis is recommended.

**No malaria in urban areas.

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ATORVASTATIN, a 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitor is indicated for the treatment of primary hypercholesterolemia and mixed dyslipidemia.[1] Atorvastatin has been shown to be effective in reducing low-density lipoprotein (LDL) cholesterol and apoprotein B production.[2]

Mechanism of Action and Pharmacology

Atorvastatin, [R - (R*,R*)] -2- (4-fluorophenyl) -β, δ-dihydroxy-5- (1-methylethyl) -3 phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptaonic acid calcium salt(2:1), is a potent inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMGCo-A) reductase. The chemical structure of atorvastatin is shown in Fig. 1. HMG-CoA reductase catalyzes the conversion of HMG-CoA to mevalonic acid, which is the rate limiting step in cholesterol synthesis. The decrease in cholesterol synthesis causes a compensatory increase in hepatic LDL-receptor activity and may also decrease hepatic production of LDL cholesterol. The increased receptor activity lowers LDL-cholesterol levels by increasing hepatic uptake of LDL and its precursors, IDL (intermediate density lipoprotein) and VLDL (very low density lipoprotein) cholesterol. The increased removal of IDL and VLDL explains the modest decrease in triglycerides observed with older HMG-CoA reductase inhibitor drugs; the marked triglyceride-lowering effect of atorvastatin appears to be due to increased removal of triglyceride-rich VLDL. The ability of atorvastatin to lower LDL concentrations in patients with homozygous familial hypercholesterolemia, who have no or few functional LDL receptors, suggests that the new drug also has a greater effect than older HMG-CoA reductase inhibitors on hepatic production of LDL cholesterol.[1,3]

Pharmocokinetics

Atorvastatin is 80% bound to plasma proteins and distributes to the liver, spleen, and adrenal glands. After oral absorption, atorvastatin, undergoes extensive hepatic extraction, ranging from 46% to 79%. Atorvastatin is metabolized to active ortho- and parahydroxylated derivatives and an inactive beta-oxidation product. The parent compound has a half-life of 14 hours and time-to-peak serum concentration of one to two hours (maximal reduction in plasma cholesterol and triglycerides in two weeks). In addition, atorvastatin is primarily excreted by the bile. Thus, food could markedly alter systemic HMG-CoA concentrations by influencing hepatic extractions without significantly changing the amount of drug absorbed from the gastrointestinal tract and reaching the liver. Despite changes in the systemic plasma concentration, little effect on serum lipids is expected, because the liver is the primary site of cholesterol clearance. Atorvastatin is subject to first-pass metabolism. It is known that liver blood flow and liver size decrease with age in humans. Plasma concentrations of atorvastatin will depend on hepatic clearance, which is influenced by hepatic blood flow, liver size, bile flow, and intrinsic clearance. Therefore, observed age-related differences in systemic drug exposure may be due to these hepatic changes. Correlations between plasma concentrations of HMG-CoA reductase inhibitors and therapeutic effects are not observed. Results of subsequent safety and efficacy trials should help clarify the clinical significance of age and gender -related differences in the pharmacokinetics of atorvastatin.[3,4]

Clinical Trials

A six-week, double-blinded, multicenter evaluation of lipid parameter responses to different dosages of atorvastatin in patients with primary hypercholesterolemia was conducted. After completing an eight-week placebo-baseline dietary phase, 81 randomly assigned patients with elevated LDL cholesterol (> 4.14 but < 6.21 mmol/L) and normal levels of trigylcerides (3.39 mmol/L) were assigned to receive 2.5, 5, 10, 20, 40, or 80 mg atorvastatin once daily for six weeks. Plasma LDL cholesterol reductions from baseline were dose related, with 25% to 61% reduction from the minimum dose to the maximum dose

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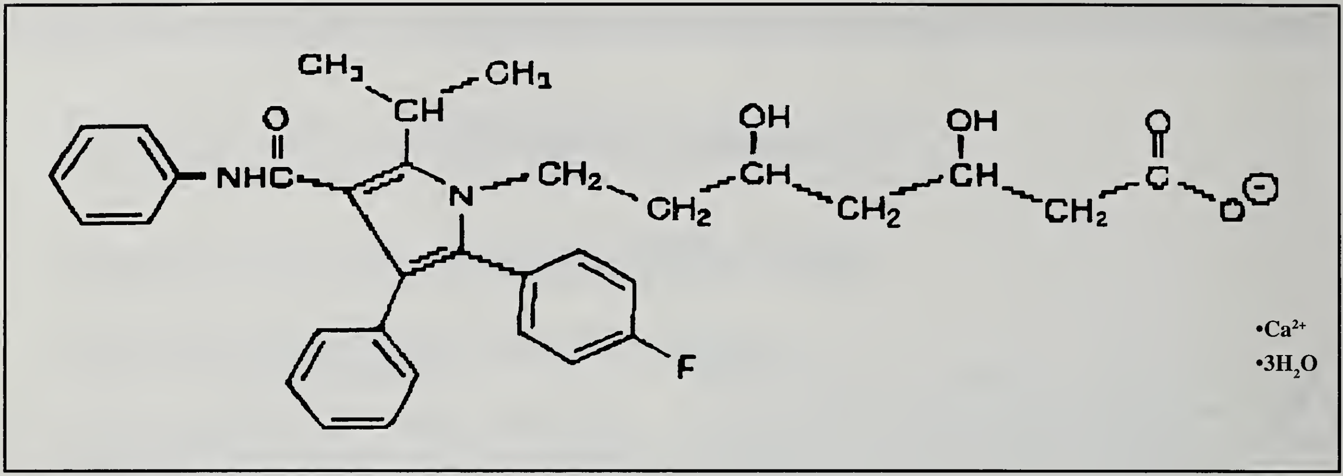

Figure.—Chemical structure of atorvastatin.

of 80 mg atorvastatin once a day. Patients treated with 2.5 and 80 mg atorvastatin had reductions in total cholesterol of 17% and 46% respectively, and reductions in apo B of 17% and 50% respectively. Reductions in triglycerides from baseline values were 25% or greater for patients with 5, 20, 40, or 80 mg atorvastatin. No drug-related serious adverse events were reported. There was a dose-related increase in the number of patients with mild elevations (one to two times the reference range) of AST and ALT. In this study, atorvastatin was well tolerated by hyperlipidemic patients, had an acceptable profile, and provided greater reduction in cholesterol than other previously reported HMG-CoA reductase inhibitors.[5]

A randomized, double-blind study was performed at nine community and university-based research hospitals in Australia. One hundred seventy-seven patients between ages 18 and 80 years with baseline low-density-lipoprotein (LDL) cholesterol ≥ 4.14 and ≤ 7.76 mmol/L (160 and 300 mg/dL, respectively) and trigylcerides ≤ 4.52 mmol/L received once daily dosing with atorvastatin 10 mg or simvastatin 10 mg. At week 16, the dose of medication was titrated to atorvastatin 20 mg or simvastatin 20 mg if patients did not meet LDL cholesterol target of ≤ 3.36 mmol/L (130 mg/dL). Efficacy was reported as percent change from baseline in LDL cholesterol, total cholesterol, very low density lipoprotein cholesterol, total trigylcerides, high density lipoprotein cholesterol apolipoproteins Al and B, and lipoprotein(a). Atorvastatin caused significantly greater reductions from baseline than did simvastatin for LDL cholesterol, total cholesterol, very low density lipoprotein cholesterol, trigylcerides, and apolipoprotein B ($P<0.05$). No patient in either treatment group had clinically important elevations in creatinine phosphokinase or aspartate aminotransaminase. No serious adverse events were considered associated with treatment. With atorvastatin 10 mg, 46% of the patients achieved LDL cholesterol target goal by week 16, whereas only 27% of the simvastatin patients achieved the target goal at the 10 mg dose.[6]

In three multicenter, double-blind studies in patients with hypercholesterolemia, atorvastatin was compared to HMG-CoA reductase inhibitors. After randomization, patients were treated for 16 weeks with either atorvastatin 10 mg per day or a fixed dose of the comparative agents. The effect on clinical outcomes of the differences in lipid-altering effects between treatments shown is not known.

Table 1.—Mean Percent Change from Baseline at End Point
Double-blind, Randomized, Active-controlled Trials

Treatment (Daily Dose)	N	Total-C	LDL-C	ApoB	TG	HDL-C
Study 1						
Atorvastatin 10 mg	707	–27	–36	–28	–17	+7
Lovastatin 20 mg	191	–19	–27	–20	– 6	+7
Study 2						
Atorvastatin 10 mg	222	–25	–35	–27	–17	+6
Pravastatin 20 mg	77	–17	–23	– 9	– 9	+8
Study 3						
Atorvastatin 10 mg	132	–29	–37	–34	–23	+7
Simvastatin 10 mg	45	–24	–30	–30	–15	+7

Table 1 does not contain data comparing the effects of atorvastatin 10 mg and higher doses of lovastatin, pravastatin, and simvastatin.[7]

Adverse Drug Reactions

In controlled clinical trials of 2,502 patients, the most frequent adverse events thought to be related to atorvastatin were constipation, flatulence, dyspepsia, and abdominal pain. Dose related increases in aminotransferase activity have occurred in patients taking atorvastatin. Increases more than three times normal occurred in 0.2% of patients taking 10 mg/day and in 25% taking 80 mg/day. After dosage reductions or discontinuation of the drug, aminotransferase activity returned to or near pretreatment levels without sequelae. Uncomplicated myalgias have occurred in some patients taking atorvastatin. It is recommended that liver function tests be performed before the initiation of treatment, at six and 12 weeks after initiation of therapy or elevation in dose, and periodically (eg, semiannually) thereafter. Should an increase in ALT or AST of > 3 times upper normal limits persist, reduction of dose or withdrawal of atorvastatin is recommended. Atorvastatin is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases.[1,7]

Administration and Dosage

The patient should be eating a standard cholesterol-lowering diet before receiving atorvastatin and should continue on this diet during treatment with atorvastatin. The recommended starting dose is 10 mg once daily. The dosage range is 10 to 80 mg once daily. Atorvastatin may be administered as a single dose at any time of the day, with or without food. Therapy should be individualized according to the goal of therapy and response as established by NCEP Guidelines. After initiation and/or upon titration of atorvastatin, lipid levels should be analyzed within two to four weeks and dosage adjusted accordingly.[7]

Cost

Lipitor® average wholesale price (AWP)[8]	
10 mg tablet	$1.46
20 mg tablet	$1.92
40 mg tablet	$2.31

Place in Therapy

Variations in study designs have indicated conclusive information in regard to the most cost effective use of atorvastatin. Study results may vary depending on risk factors for coronary heart disease, target LDL level, and doses of atorvastatin and comparative agents. Atorvastatin has a rapid onset of action; approximately 90% of the LDL cholesterol reduction from baseline occurred within the first two weeks of treatment.[5,7] For patients at increased risk for atherosclerotic vascular disease and baseline LDL exceeding 200 mg/dL potential reductions up to 60% may be possible[5,9] Because of cost issues, doses greater than 10 mg should be reserved for patients with severe hypercholesterolemia requiring reductions in LDL >50%.

Conclusion

When considering a HMG-CoA reductase inhibitor for their formulary, pharmacy and therapeutics commmittees should consider relative effectiveness of the inhibitors in various hyperlipidemic subtypes and when used as a primary prevention or secondary prevention cholesterol lowering agent. Committees should also consider known side effects, drug interactions, cost of therapy, as well as each drug's use in special patient populations. Although a 50% to 60% reduction in LDL can be achieved by combining several lipid-modifying combinations drugs, no single agent has been reported to produce this result. Clinical trials suggest that atorvastatin, with its enhanced efficacy, may provide adequate therapy for a large number of dyslipidemic patients, including those previously treated with multiple therapies. Becaue of its unique ability to normalize both cholesterol-rich and triglyceride-rich particles, atorvastatin is a promising candidate for monotherapy in a broad range of patients including those with varying degrees of hypercholesterolemia and hypertriglyceridema.[5,10]

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As Life Ebbs, So Does Time to Elect Comforts of Hospice

SHERYL GAY STOLBERG

AFTER eight years of working in a nursing home, Alaine Dougherty was no stranger to death. When terminal cancer of the esophagus was diagnosed in her mother last April, she knew precisely what she wanted—or, rather, did not want: "I didn't want my mom to suffer, and I didn't want all the craziness."

Despite Mrs. Dougherty's wishes for her mother, Marilyn Snyder's final months were filled with confusion and pain. She was shuttled from one specialist to another: a surgeon, an oncologist, a radiologist, a cardiologist, a gastroenterologist. She was frightened and weak, and when she stopped eating, six weeks before she died in July, her son and daughter knew the end was near.

But nobody else, it seemed to Mrs. Snyder's children, would admit that their mother was dying, least of all her doctors. None suggested hospice care, the program rooted in the philosophy that by focusing on the comfort and spiritual needs of the terminally ill, death can be made less difficult for patients and families.

By the time hospice nurses were sent to Mrs. Snyder's bedside, at her daughter's insistence. it was too late to do her much good. She died within the week, before even the hospice chaplain had a chance to visit.

"She died this horrible, chaotic death," Mrs. Dougherty said, still tearful and angry nine months later. "People say to me, 'You're angry that your mother died.' What I'm angry about is the treatment from her doctors in not letting her die a peaceful death."

Mrs. Snyder's difficulty in obtaining hospice care is troubling, experts say, but not uncommon. As medical professionals campaign to improve care of the dying, experts agree that hospices offer what many call a "good death." But they say people often enter hospice care too late to take full advantage of it, sometimes just days, even hours, before death.

"This is not hospice care," complained Carolyn Cassin, the president of Hospice of Michigan, one of the largest hospice agencies in the nation. "This is brink-of-death care."

The reasons are partly economic. Medicare, the government-financed insurance program for older Americans, covers hospice care for only the last six months of life, and most private insurers, if they cover hospices at all, have followed suit. But most people spend years deteriorating from chronic illnesses. Like heart disease, and their doctors have difficulty predicting when they have less than six months to live.

Even cancer and AIDS patients, who follow a predictable trajectory toward death, often enter hospice programs late. That is because Medicare, which covers 80 percent of hospice patients, requires patients to give up aggressive treatment, or curative care, in favor of palliative care, therapy that is intensive but designed only to comfort.

That can be a difficult decision. Doctors equate hospice with giving up on their patients, and patients equate it with giving up on themselves.

Dr. Nicholas Christakis, an expert in end-of-life care at the University of Chicago, explained, "Patients will say, 'Doctor, I want to go to hospice,' and the doctor will say, 'No, no, you're not that sick yet.'"

Less than 20 percent of the dying people in this country use hospice care. The National Hospice Organization, which represents the nation's 3,000 hospices, estimates that 450,000 people used the service in 1996.

Written by SHERYL GAY STOLBERG for *The New York Times*. Copyright ©1998 by *The New York Times Company*. Reprinted by permission.

Patients' stays are growing shorter. In 1993, a study by Dr. Christakis found, the median time spent in hospice care was 36 days, and three-quarters of all hospice patients died within three months of admission. In 1995, the most recent year for which the national hospice group has figures, the median stay was 29 days, five months shorter than what most insurance allows.

Many people envision hospices as homey places where people go to die; that is the norm in England, where hospice programs got their start. But in the United States hospice agencies typically send nurses and social workers to visit dying people at home. Their services run the gamut, from providing special mattresses to alleviate bedsores to encouraging families to come to terms with death.

According to Dr. Christakis, studies show "incredibly high satisfaction with hospice care on the part of patients and their families." According to the Institute of Medicine, researchers have found that hospice patients are more likely than others to die in a manner consistent with their wishes, at home and free from pain. Mrs. Snyder's children credit hospice nurses with finally making their mother comfortable, if only for a few days. "They should have been there from the very beginning," Mrs. Dougherty said.

In centuries past, hospices were way stations for religious pilgrims; contemporary hospice programs also have a spiritual bent. Dr. Ira Byock, author of "Dying Well" (Riverhead Books, 1997), described the hospice philosophy this way in an interview: "Death is more than a set of medical problems to be dealt with. It is fundamentally a personal experience."

Patients like Mrs. Snyder, however, largely miss that personal experience. An examination of her dying months, pieced together from a review of hospice records and interviews with her daughter, Mrs. Dougherty, her son, John Snyder, two of her doctors, and the hospice nurse who cared for her, reveals how high-tech medicine can inadvertently deprive dying patients of what most say they want: a death free from burdensome procedures and machines.

The Patient

Outlook is bleak, given the cancer.—Marilyn Jean Snyder had always been a robust, independent woman. A graduate of the University of Iowa, she struck out on her own after a difficult marriage and pursued a career in library sciences. Her passion was the Civil War; at the time of her death, she was writing a book based on the letters of her great-great-uncle, a lieutenant colonel in the Union Army.

Last Easter, Mrs. Snyder, 66, who lived alone in a condominium in Annandale, Va., called her daughter at home in Bethlehem, Pa., to say she felt a spasm in her throat. Within two weeks, Mrs. Snyder's doctors at the Kaiser Permanente health maintenance organization had found a cancerous tumor the size of a fist engulfing her esophagus.

"Most of these cancers are not cured," said Dr. Mutombo Kankonde, 40, the oncologist who treated Mrs. Snyder. The median survival for patients like her, Dr. Kankonde said, is six to nine months. Still, he hoped to be able to treat her, to slow the progression of her disease.

Mrs. Snyder's first decision was whether to have surgery to remove the diseased section of the esophagus. The operation took place on April 14. It did not go well; Mrs. Snyder's cancer had spread into the lymph nodes around her stomach.

The plan was to begin chemotherapy and radiation as soon as Mrs. Snyder was well enough to withstand it. But her recovery was fraught with complications: chest pains, high blood pressure, pneumonia. Suddenly, her 39-year-old son, a computer expert, and 42-year-old daughter, a housekeeping supervisor at a nursing home, found themselves going to work, taking care of children and nursing a sick parent, all at once.

They spent May trying to get their mother settled, moving her from the hospital to her apartment to a nursing home and back home again. With her condition deteriorating, her treatment was put on hold. Then, in June, Mrs. Snyder, who relished a good meal so much that it was a family joke even at her memorial service, did something that her children found difficult to comprehend. She stopped eating.

This was a sign, experts say, that Mrs. Snyder was dying. "People who are in the late phase of dying are not hungry," said Dr. Diane E. Meier, an expert in end-of-life care at Mount Sinai Medical Center in New York City.

June 19 was Mrs. Snyder's 67th birthday. Her daughter had come from Pennsylvania to visit, bringing presents that were never opened. Instead, the family spent the day at the hospital. Mrs. Dougherty was terrified that her mother was starving to death; she said an oncology nurse suggested that her mother be hooked up to an intravenous feeding system.

The system requires doctors to implant a surgical shunt just under the collarbone, so that an intravenous line can pump a nutrient-rich formula directly into the bloodstream. This aggressive treatment would fight the dying process, although Mrs. Snyder's children said they did not realize it at the time.

On June 27, Mrs. Snyder got a new primary care physician, Dr. Charles Brennt, a 35-year-old internist. "Prognosis is grim," Dr. Brennt wrote in his notes after examining her, he said. But he added that he was reluctant to suggest hospice care, primarily because his colleague, Dr. Kankonde, was still hoping to offer life-prolonging chemotherapy.

"You certainly don't want to do something that would conflict with the oncologist," Dr. Brennt said.

The Hospice

Doctor decides to delay referral.—It was not until July 7 that Mrs. Dougherty, eager to get additional nursing care for her mother, called the Hospice of Northern Virginia. Founded 20 years ago in a church basement in Arlington; the agency had grown rapidly, when the file was opened on Marilyn Snyder, she became its 18,078th patient.

Hospice records show that when a representative called Dr. Kankonde, the oncologist, he declined to refer Mrs. Snyder. In an interview, he noted that hospice rules permit patients to receive chemotherapy—so long as the treatment is palliative, and not designed to prolong life. He also said he liked to get his patients into hospice as early as possible "because it is a critical support for the patient," but that he would have to look at Mrs. Snyder's chart to see why he declined in her case.

But even though Mrs. Snyder's children gave Kaiser Permanente permission to release her records, officials at the health maintenance organization declined to do so and instructed Dr. Kankonde not to comment further.

In any event, outside experts said, his decision was not unusual. "There are very positive impulses motivating physicians," Dr. Meier, of Mount Sinai, said. It is very painful to say to someone, 'It's time to stop chemo and radiation.'"

Some argue that the health care system itself needs to be changed. Dr. Joanne Lynn, who directs the Center for Care of the Dying at George Washington Umversity, has proposed a new system, which she calls "medicaring," that would enable patients to receive the kind of comfort hospice provides without giving up their right to curative treatment. The Health Care Financing Administration which runs the Medicare progran, is considering the idea, and Dr. Lynn is planning some pilot projects to prove it might pay for itself.

A good end-of-life care system, Dr. Lynn said, would allow families to look back on a death "and realize that it was a meaningful time, that it wasn't just being battered from pillar to post."

Battered, however, is precisely how John Snyder and Alaine Dougherty felt; they were desperate for nursing help. "At some point," Mr. Snyder said, ' you need to give up and get those services. The doctors have to say, 'Look, it's not going good.'"

That finally happened in mid-July, when Mrs. Snyder's cancer spread to her lungs. She was admitted to a nursing home; Dr. Brennt referred her to the hospice, whose nurses would visit her at the home. He recalled his words to the oncologist: "The writing is on the wall. It's time to work on the care and comfort."

The Final Days

Sharing laughs, planning a service.—Karen Lucas was the hospice nurse who cared for Mrs. Snyder. She derives her passion for hospice from personal experience: trauma her mother suffered in caring for her dying father. She finds the work exhausting and emotional, all the more so when a patient enters hospice care as close to death as Mrs. Snyder was

"I never really had a chance to have a conversation with Marilyn." Mrs. Lucas said. "Each time I saw her, she was in crisis and too tired to talk."

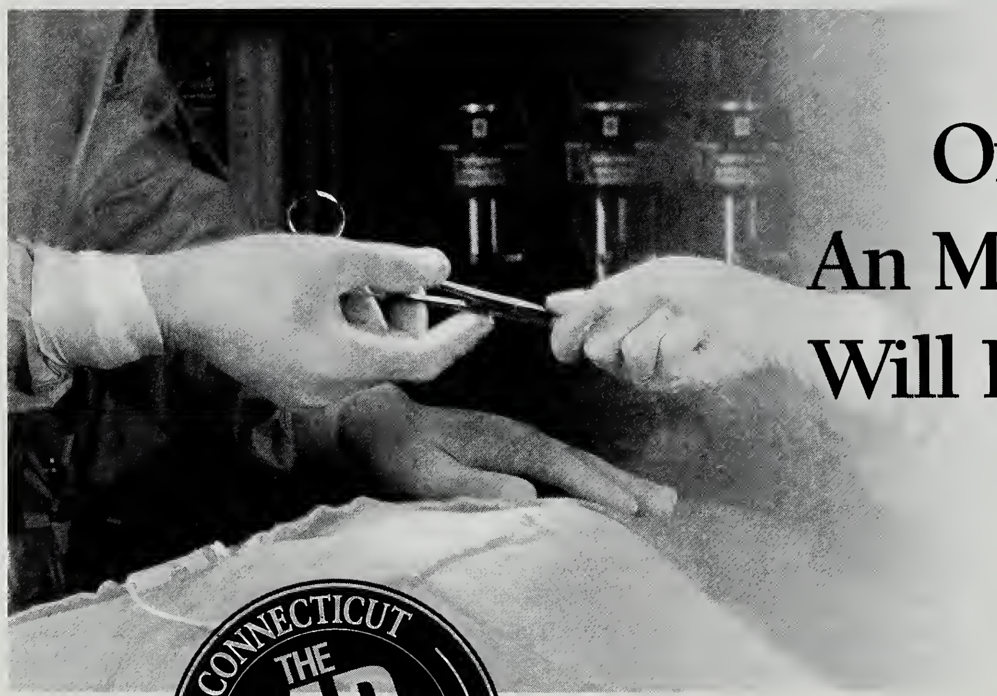
The nurse ordered a sedative, and she cut back and then eliminated the nutrition. Meanwhile, a hospice social worker encouraged Mrs. Dougherty and her brother to ask their mother about burial plans while she could still talk. Mrs. Snyder, it turned out, wanted to be cremated, and she wanted a memorial service at the historic Civil War battlefield in Manassas, Va, where the great-great uncle whose letters she had been transcribing had fought.

"It was just like they told us," Mrs. Dougherty said. "You have to have everything straightened out to die."

On Friday, July 18, Mrs. Snyder had her first good day in months. She took a wheelchair ride to the nursing home beauty salon to get her hair done. She chatted about her book. Even sedated, she made her children laugh. "She said, 'I'm not going to make it to my memorial service.'" Mrs. Dougherty remembered. "I said, 'Why, Mom?' She said. 'It's just going to be too emotional.'"

Five days later, with a good friend, a fellow Civil War buff, by her side, she died in her sleep.

In A Room Where There's No Room For Error...



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The AMA's Evaluation and Management Coding Conference of 27 April 1998

STEPHEN R. LEVINSON, M.D.

SUMMARY—The evaluation and management (E/M) coding system has been evolving since it was first introduced in Current Procedural Terminology (CPT) in 1992. The evolution has included E/M coding, Documentation Guidelines of 1995, and the recently introduced Documentation Guidelines of 1997.

In response to overwhelming concerns by physicians about "burdensome" documentation requirements of the new 1997 guidelines (concerning the physical examination section of medical records), the Health Care Financing Administration (HCFA) has delayed implementation of this new section. The American Medical Association (AMA) and HCFA are working together to bring the requirements into alignment with what physicians consider appropriate documentation for physical examination. At the same time, they are re-examining all of E/M coding and documentation, with a goal of modifying the system to best fit with requirements for good medical care and reasonable documentation. In addition, HCFA stresses that the current (1995) requirements for coding and documentation remain in place. To assure appropriate payment by their carriers, Medicare will continue to audit medical records based upon the E/M coding section of CPT and upon 1995 documentation guidelines. Physicians are encouraged to communicate with CSMS regarding their requirements and recommendations.

ON 27 April 1998, the AMA convened a national review and workshop on Evaluation and Management (E/M) coding and documentation in Chicago. This "fly-in" was attended by over 300 invited physicians, representing state medical societies, specialty societies, and other medical associations. The meeting was part of the response to the 1997 revised documentation guidelines that physicians say are "unfair and burdensome." The AMA and HCFA state they are working to accomplish "substantial improvements" to this portion of E/M coding.

The AMA announced three objectives for this workshop:

1. *Advocacy,* to assure that physicians are protected from unwarranted fraud and abuse penalties.
2. *Re-evaluation* and refinements to the proposed new documentation guidelines and a re-assessment of the E/M documentation and coding system as a whole.
3. Obtain further *delay* in implementation of the new documentation guidelines to permit refinements to the system and provide time for adequate physician education in a revised new system.

Structure of the Meeting

All members of the group initially attended a single session for information and questions. The session included initial presentations by leaders of the AMA, HCFA, the office of inspector general, and the CPT executive committee. This was followed by 60 minutes of audience comments. Next, the CPT editorial committee presented a "new framework" for documentation and coding. This introduced a set of potential modifications to the physical examination section of the medical record, as well as some additional changes to the other components of E/M coding.

STEPHEN R. LEVINSON, M.D., a Trumbull otolaryngologist and a member of the CSMS Committee on Medicare, attended the April 27 AMA E/M Conference. Also in attendance were NEIL BROOKS, M.D., of Rockville, in his capacity as current president of the American Academy of Family Practice, and ROBERT J. BRUNELL, CSMS director of scientific affairs.

The afternoon meetings consisted of six open forum discussion groups running for 90 minutes. The sessions were then repeated so that each attendee participated in two of the discussions. These sessions examined the following topics in detail:

- History section of E/M documentation
- Examination section of E/M documentation
- Medical decision making section of E/M documentation
- Training and education issues
- Pilot testing, evaluation, maintenance, and monitoring
- Communications and advocacy strategy

Each session was coordinated by two leaders from AMA and/or HCFA. These sessions involved active input from the attendees to help prepare for the next steps in guideline development, training, and prototype testing.

Review of Evaluation/Management Coding and Documentation Guidelines

The E/M coding system was introduced in 1992 to fulfill several important physician requirements. The system design reflects physician work, thereby achieving compatibility with the RBRVS approach to valuation of medical care. Critically for physicians, the E/M system establishes a standard which prevents the imposition of multiple and random outside rules; it also stops extensive and inconsistent downcoding by Medicare carriers. Current appraisal shows that documentation will be utilized both for payment issues and for utilization review.

The AMA leadership outlined an extensive set of goals for this current review of coding and documentation. These include:

- Assure that all parties are playing by a standard set of rules, defined with precision.
- Address physician concerns regarding HCFA penalties for fraud and abuse.
- Address physician concerns regarding complexity of the *new* documentation and coding requirements (the proposed 1997 changes to physical exaaination documentation).
- Work cooperatively with physicians to assure a fair standard for documentation.
- Work cooperatively with HCFA to assure accurate implementation—physicians must know all the review criteria utilized by HCFA carriers, and HCFA must implement these uniformly throughout the country.

Current Status of Coding and Documentation

An auditor from the Congressional Financial Office (CFO) presented findings of their audit of HCFA payments during 1996 and 1997. These demonstrated significant occurrence of payments by Medicare carriers for improperly billed E/M services. Twenty-four percent of audited physician claims were not in compliance. The CFO projected that such overpayments by Medicare total approximately six billion dollars per year. They also reported that the three errors most frequently responsible for these problems were:

- Insufficient or absent documentation
- Lack of medical necessity
- Improper coding

HCFA Response to Current Concerns

The AMA has received a letter from the Director of HCFA outlining their position on the disputed 1997 physical examination guidelines and on working with the AMA to review and improve examination documentation requirements. The letter specifically addresses AMA and physician concerns, while also stressing that physician responsibilities are continuing under the E/M requirements of the 1995 documentation guidelines.

HCFA stated that they recognize physician concerns, and they are committed to addressing and correcting perceived flaws in the documentation system to achieve workable guidelines. To achieve this goal, they agree to further delay of implementation of the 1997 guidelines in order to allow additional time for revision and training.

- HCFA also directly addressed physician concerns about the threat of accusations of "fraud and abuse." The letter assures that there will be a distinct separation of "coding errors" from "fraud." It emphasizes that there will be no prosecution for simple billing errors or simple negligence. Specifically, for fraud to be claimed, there must be intent to defraud or a pattern of improper billing practices. However, the letter continues that fraud may also result from "deliberate ignorance or reckless disregard" of coding and documentation requirements.
- Finally, HCFA also directly addresses its assessment of coding and documentation requirements while new modifications are developed and implemented. The letter emphasizes the need to maintain the integrity of the Medicare system and further stresses that HCFA is required by Congress to assure that services provided match the code and payment level requested by physicians. As a consequence, while AMA and HCFA are modifying the new documentation requirements, physicians will continue to be held responsible to comply with the E/M coding and documentation guideline requirements that have been in place since 1995. Medicare carriers will continue their audits based on these guidelines. (The letter instructs that Medicare audits will also give credit for any physicians using the now-deferred 1997 documentation guidelines.)

Blueprint for Guideline Modification

Summarizing the meeting's discussions, including input from HCFA, AMA leaders project that over the next several months there will be ongoing evaluation of recommendations and further refinement of documentation guidelines. The stated goal is for these guidelines to reflect and be compatible with quality medical care. The primary focus of this review will be the physical examination. There will also be consideration for fine tuning of the other coding components, while the basic structure of the system remains intact. This review phase will be followed by pilot projects, with pertinent training for physicians to assure appropriateness and suitability of the improvements; further modifications will be added if indicated. Finally, there will be extensive training in the refined system to assure uniform understanding of E/M coding and documentation principles, prior to official implementation by HCFA. The membership also predicts that the policies accepted by HCFA will be adopted by private insurers and managed-care carriers as well.

Summary and Conclusions

The AMA's stated goals for the meeting of 27 April were achieved through a cooperative effort of AMA leadership, HCFA leadership, and concerned physicians of every specialty and region.

- HCFA has agreed to the AMA's request for further delay in implementation of the 1997 documentation guidelines.
- HCFA has addressed the issue of unwarranted fraud and abuse penalties, clarifying the difference between simple billing errors or simple negligence *vs* a pattern of consistent errors or intent to defraud. AMA will continue to closely monitor potential problems and evaluate any situation where physicians feel these rules have not been properly applied.
- AMA has established the mechanism to re-evaluate and refine documentation guidelines for physical examination. At the same time, the committees are fine tuning the documentation and coding system as a whole.

While changes to the E/M and documentation system are being refined, physicians must recognize that they continue to be responsible for the coding principles and documentation guidelines that have been in place since 1995. Physicians should work with their staffs to understand the current rules of documentation and coding and to assure that their office procedures are in compliance with these standards. This should also permit a smooth transition when the modified guidelines are introduced.

Physicians are also encouraged to communicate with CSMS regarding their requirements and their recommendations as the E/M system continues to evolve.

The following letter from Nancy-Ann Min Deparle, HCFA Administrator, was sent to Dr. Wootton regarding the Evaluation and Management Guidelines. The letter demonstrates a willingness on the part of HCFA to work with physicians to develop guidelines that "do not impose requirements in excess of those associated with clinically appropriate medical record-keeping practices." Further, in another positive step for organized medicine, Ms. Deparle has instructed carriers to continue to use both the 1995 and 1997 Guidelines until the revision have been completed and there is an "adequate period of time for testing and education." For more information, refer to the letter.

Department of Health and Human Services
Health Care Financing Administration
Washington, DC 20201

April 24, 1998

Percy Wootton, M.D.
President
American Medical Association
515 North State Street
Chicago, Illinois 60610

Dear Dr. Wootton:

I am writing to you about the Documentation Guidelines for Evaluation and Management Services (E/M), because I continue to hear physicians express concerns about them. I thought it would be helpful to provide you with the Health Care Financing Administration's (HCFA's) views on the Guidelines, the process for improving them, and the increased emphasis on accurate billing and proper documentation. Understandably, physicians are reacting to flaws in the Documentation Guidelines that we are committed to fix. Also, many physicians fear they will be unjustifiably targeted for fraud and abuse investigations as a result of simple coding errors. I want to do what I can to allay those fears.

As stewards of the Medicare program, HCFA must be sure the payments we make on behalf of our beneficiaries are for medically necessary and appropriate services, and that the services have been accurately reported. Our FY 1991 CEO Audit, which was released April 24, indicates that while we are making progress in reducing inappropriate payments, we still have much work to do, particularly in the area of ensuring that documentation for physician claims is adequate. Inadequate or no documentation is the principal cause of the improper payments identified in the CFO audit report.

HCFA needs to be confident that Medicare carriers are reviewing medical records in a consistent manner. Physicians need assurances that they are billing appropriately and have adequate documentation in the event of an audit. A workable version of the Documentation Guidelines is an essential tool for both physicians and our carriers. Further, improving program integrity serves the interest of Medicare, its beneficiaries, and its providers, including physicians.

I have heard that physicians believe the 1997 Documentation Guidelines that the American Medical Association (AMA) and HCFA developed together are too complex and burdensome. The most troubling concern is that some physicians believe the new Guidelines will divert too much physician time and attention from patient care to paperwork. I believe we can and must work together to improve the Guidelines so they do not impose requirements in excess of those associated with clinically appropriate medical record-keeping practices.

I understand that the written comments you received in mid-March contained a number of thoughtful suggestions. I have asked Robert A. Berenson, M.D., the new director of HCFA's Center for Health Plans and Providers, to participate in your "fly in" meeting today. We look forward to discussions about implementation issues, as well as the content of the Guidelines themselves.

In December 1997, HCFA agreed to your request that carriers use both the 1995 and 1997 versions of the Documentation Guidelines to evaluate claims until 1 July 1998. When we set that July 1 date, neither the AMA nor HCFA fully understood the magnitude of the problems with the 1997 Guidelines. I think it is unrealistic to expect that the revisions can be completed by that date and it is clear that an additional period is needed for testing the Guidelines as well as for education of physicians and carriers.

Therefore, I am directing carriers to continue to use both the 1995 and 1997 Guidelines, whichever is more advantageous to the physician, until the revisions have been completed and there has been an adequate period of time for testing and education. Since there is still uncertainty about how quickly that work can be done, I think it is premature to set an implementation date now. Dr. Berenson and his staff will report to me in the early fall on the status of the revision efforts and the projected schedule for testing, refinement, and physician education. I anticipate using that information to set a final date for implementation of the revised Guidelines that will allow ample time for completion of the pre-implementation activities.

We believe the final product will be strengthened by the broad physician participation in the revision process. Working together, we can make the Guidelines easier to understand and we can sharpen the focus so that only documentation directly related to the care provided is required.

Let me turn to the broader issue of the emphasis on fraud and abuse, particularly the provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regarding sanctions for coding errors. Civil monetary penalties may now be assessed for coding that the person knows, or should know, will result in greater payments than appropriate. However, the statute is very clear that there must be a pattern or practice of such behavior.

I want to assure you that physicians will not be punished for honest mistakes and we will not make referrals to the Office of the Inspector General for occasional errors. To be certain there is no misunderstanding about this, I have asked my staff to issue an instruction to the carriers reminding them of our long standing policy that referrals are to be made to the Office of the Inspector General for possible sanctions only after the carrier determines the situation was not caused by error and there is evidence of intentional improper billing practices. We have to believe there is some level of fraudulent intent before we make any referrals. Sanctions are intended for physicians who act in "deliberate ignorance" or with "reckless disregard" of the truth or falsity of information. For criminal penalties, the standard is that the provider had "knowing and willful" intent to defraud the government.

We are at a critical juncture in the development of the Documentation Guidelines. I am confident that by working together we can develop revised Documentation Guidelines that will meet our needs to assure that Medicare payments are appropriate without imposing undue burden on physicians. I hope your meeting is a productive one that will move us closer to that goal.

Sincerely,
Nancy-Ann Min DeParle
Administrator

Commentaries

Back to the Bedside

It was odd. As I left Mrs. Jones' room late that evening, I suddenly felt more focused and more confident than I had been the entire week before. Although the news that I gave Mrs. Jones and her family was not particularly good, it was news that I was certain she and her family members needed to hear and needed to hear now. The diagnosis was still unclear, but there was no doubt in my mind that the mass in her adrenal gland needed to be biopsied.

As I made my way to the nurses' station and pulled her chart out of the rack, I couldn't quite pinpoint the reason why I felt as good as I did at that particular moment. It suddenly struck me that during my conversation with her family, the face to face "give and take" and methodical discussion of the diagnostic possibilities causing Mrs. Jones' weight loss, fevers, and adrenal mass enabled us to arrive at a clearly defined and indisputable decision point. It was clearly the right thing to do for this particular patient at this particular moment.

I then thought a bit longer and realized that clarity of thought, certainty of decision making, and clear differentiation between right and wrong was something I was able to achieve very infrequently lately. Sometimes I found my medical decisions influenced by things like subspecialty capitation, preferred formularies, at-risk patient populations, withhold, standard of care, patient satisfaction, utilization management, out-of-plan migration, interqual criteria, clinical pathways, etc., etc., etc.

Despite the fact that I consider myself a strong patient advocate, I wondered how my decisions may be consciously or subconsciously driven by many of these conflicting forces. As many of my colleagues know better than I, the ability to practice medicine is virtually impossible when you are trying to please yourself, your partners, your peers, managed-care organizations, your local MSO, your personal accountant, your local medical director, your HCQIP director, your risk manager, your family and, oh yes, your patients. Recently when seeing certain patients I have wondered "Who am I trying to satisfy today?," as I've attempted to solve their particular problems. As I recognized that evening, very often at a patient's bedside I could find the clarity of thought and surety of purpose that physicians need in order best to care for their patients. At the bedside, where patients are perhaps most vulnerable, things often seem clearer in terms of what is right, what is less right, and what is wrong.

Potential conflicts of interest surround physicians daily as they try to maintain a fine balance between good medical care and the liability issues and cost constraints that are always lurking around every corner. With the various "hats" that I wear, I frequently find myself looking for solutions that will please everyone—a most difficult, if not impossible task. It's curious that at a patient's bedside —a place where in a sense the pressure of medicine can be at its highest as you try to satisfy the expectations and hopes of the patient, her family, the nursing staff, and yourself—I actually find it to be one of the few places these days where decisions are clarified and the various conflicting interests, at least for the moment, are minimized. At the bedside, the realization comes quickly that your first and foremost responsibility is to your patients—to somehow control their pain, allay their fears, clarify their questions, and hopefully cure their illness *with whatever resources you may require.*

In these days of managed care, a place where conflict of interest is less and decision making is simpler, is a most welcome refuge. I believe that a "return to the bedside" for many of us can be a daily opportunity to recharge our batteries, and to make important decisions that are less encumbered by the many conflicting forces of managed care, as we see people in their most vulnerable of circumstances and in the greatest need of our advocacy. Perhaps, with our daily bedside patient encounters, we may still find medicine's collective soul and do what we know to be intellectually correct and morally right.

Randy A. Goodwin, M.D.

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Science and Sense

"At heart he remained a physicist convinced that life itself was no more than physical chemistry ..."[1] How bizarre that Helmholtz, physician-physicist who invented the ophthalmoscope, should miss that undefined glint in the eye, spark of human soul! Physicists believe real science is physics. All the rest is stamp-collecting! Lord Kelvin said "when you cannot express it in numbers, your knowledge is of a meager, and unsatisfactory kind."[2] Physics without mathematics is unthinkable. Chemistry is reduced to atomic physics in our 20th century, atoms into quanta, matter into energy. Reductions abound. What is molecular biology if not biochemistry of life? Genetics is DNA's molecular biology in breeding populations. Evolution is organic chemistry, photosynthesis in plants, carbon-based organisms feeding, or plants, animals, oxygen, water, and solar energy, winners breeding their DNA. It all boils down to physics, the rest mere classification. What need for soul in this reduction?

We disciples of Helmholtz now make our observations in an aseptic bubble, divorced from living mortals as never before. The lengthening stethoscope distances doctor from patient. We put patients in tunnels; magnetic fields prohibit our entry. Imagine a medieval physician pressing his ear to a human breast, to know beat of heart and thrust of life! Dare we cross the moat and enter a patient's private citadel of senses? The ophthalmoscope of Helmholtz and a handshake still carry today's physician-physicist through the intimate barrier, combining warm hand of friendship with cool light of science. We silently peer into retina, not only retina to retina but brain to brain! The optic nerve is brain tract, not mere peripheral nerve. The hot-red reflex of brain blazes in our focused light. Five synapses serve the pupillary reflex. Like Helmholtz we are enraptured by dynamic physics of light, energy, and electric nerves. Photons!

Electrons! Subatomic photons make pupils constrict! Quantum physics! Mechanism beneath conscious control. If an atom were the size of an apple, an apple would be the size of Earth! The glamour of science blinds us.

Existence, life, is not reducible. Life does not boil down to atoms. Atoms are not dead or alive. Reduction, like induction, is logical theory, not demonstrable fact. Reduction is not identity. Physics, though potent, is not the only real science. Darwin never spoke calculus.

Our terrestrial brain emerges from its infantile amnesia. It never occurs to children that Earth moves. As adults we never sense Earth's great velocity, exceeding 1,000 miles a minute, in its passage around Sun. Earth is always at rest in our privacy, and always in motion in physics. Since Kepler (1571–1630) we learn Earth moves as a planet in elliptic orbit, covering equal areas in equal time. We, and Earth beneath our feet, speed up when Sun is close! This fact of physics escapes us. Kepler's third law also connects time and space, now for two planets: the squares of the periods of revolution of any two planets are as the cubes of their mean distances from Sun! Before Kepler the elliptical clues were invisible to all students of the sky. They saw only circles. "The laws of physics are not transparent to us in our direct observations of nature. They are frustratingly hidden."[3] Science is not reducible to sense. Nature loves to hide, said Heraclitus. Newton (1642–1727) deduced "the greatest generalization of the human mind,"[4] his Law of Gravitation: $F=Gmm^{1}/r^{2}$. Two bodies exert Force upon each other which varies directly as the product of their masses, and inversely as the square of the distances between them. G is always constant, no matter whether Force is between Earth and Sun, or apple and Newton's head. Newton said "All bodies whatsoever are endowed with a principle of mutual gravitation."[5] Gravitation unifies earthly and celestial physics, from an apple's fall to fall of Moon toward moving Earth, to solar tango of planets and cosmic waltz of stars. Newton's Law never convinces our bodies of speeding Earth beneath our feet, nor was the Church persuaded by Galileo (1564–1642). His telescope showed motion in heavens, Jupiter's moons, not spinning Earth. What is true in physics, constant motion of Earth, even our acceleration, is belied by our senses.

Earth moves and it does not. No psychophysics puts this contradiction to rest. Helmholtz joined logical positivists to kill metaphysics, that part of Aristotle "beyond physics." They killed in order to dissect. They left dead philosophy, analyzed to lifeless bits. Conscious life knows a different drummer, a song of celebration: To Life! Existence is beyond physics and beneath logic. Existence admits no argument. Existence is irreducible. Existence is. The riddle does not exist.

Charles W. Needham, M.D., F.A.C.S.
Norwalk

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3. Davies P: Introduction to *Six Easy Pieces,* by Richard P. Feynman. Cambridge, Mass.: Addison-Wesley Press: 1995, p XIV.
4. Feynman R: *The Character of Physical Law.* Cambridge, Mass.; MIT Press: 1995, p 14.
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Malpractice Coverage in Connecticut for the Last 30 Years

Where have we been?

I was insured with Aetna in the 1960s and 1970s. When they left I was passed on to CNA. CNA promised lower rates and more shared information. As the cost increased in the 1980s, the Connecticut State Medical Society formed its own malpractice company (CMIC) which has been going successfully for a decade and a half. Despite competition from CNA, St. Paul, and others, CMIC has garnered the greatest share of the Connecticut market.

Where are we today?

CMIC has stayed and proved itself as a true friend of the medical profession (after all, it is owned by us). CNA is closing shop in October of this year and I presume they will honor the tail insurance, especially for those who are retiring this year, as they have always promised. This group could otherwise be out in the cold; no new coverage and no tail. St. Paul, which has quietly been around since the mid 1960s, continues to write malpractice insurance. I do not personally know anyone who has insurance with St. Paul. Recently, two doctor-owned insurance companies in Massachusetts and New Jersey have been advertising and selling, or at least offering coverage, to Connecticut physicians.

The most recent insurance company to be heard from, Southern California Physicians' Insurance Exchange (SCPIE), comes to us from California. It was started by California physicians but has recently gone public, so, like the HMOs, they are a public company out to make money from the Connecticut MDs.

The "Physicians Protection Plan" which is run by the American Healthcare Indemnity Company is licensed in 44 states and the district of Columbia, and it will take over almost all of the CNA business under the same terms. Believe it or not, CNA sold the Ob/Gyn business to a different commercial entity. One gets the impression we are up for sale to the highest bidder or any group who wants to get rich at our expense.

Malpractice has changed over the last 30 years; we physicians are more aware of our responsibilities. Our handwriting has improved and is more legible. Our office staffs inform us of problems before they mushroom. The net effect of this is that those who pay the highest premiums have seen their cost diminish considerably and the low payers have seen their premiums go up.

What do we want?

The climate has changed and, to be quite honest, we have won, or at least are winning, the battle. The question now is what must we demand with our new malpractice coverage.

1. Guaranteed tail coverage for life.
2. Peer review for clinically sound and professionally fair advice on claims and underwriting decisions.
3. A company that will work with us in our trials and tribulations and won't leave us in the lurch.
4. Somebody who will take our money and *not* run.

What is in our future?

Those who have been left in the lurch by CNA must think carefully before they plunge into their next insurance malpractice experience. Talk to a colleague who has been involved—someone like me who has been involved for 30 odd years with the malpractice situation in Connecticut. I will be happy to give you the benefit of my experience.

Anthony P. Redmond, M.D.
Greenwich
AMA Delegate

Physician Liability for Suicide of Noncustodial Patient

It is every physician's worst nightmare: to be sued for malpractice—successfully—for the suicide of someone the physician barely knew, and only treated once, as an outpatient. Yet that is exactly what happened in the landmark decision of *Edwards vs Tardif.*[1] In *Edwards*, the Connecticut Supreme Court held that physicians may be liable for the suicide of noncustodial patients in certain circumstances: "We hold that a physician may be liable for a patient's suicide when the physician knows or reasonably should have known of the risk of suicide and the physician's failure to render adequate care and treatment proximately causes the patient's suicide."[2] The *Edwards* decision clarifies the law regarding the imposition of liability upon a physician for the suicide of his or her patient, in a noncustodial setting.

The Facts of the Case

The facts in the *Edwards* case are instructive. From 1981 to 1987, the plaintiff's decedent, Agatha Edwards (hereinafter "Edwards") had suffered from recurring clinical depression, for which she had been prescribed Tofranil.[3] During this time she was hospitalized for severe depression, and while hospitalized, she expressed thoughts of suicide. In December 1987, however, her physician, Dr. Tardif, concluded that her depression had resolved, and her medication was discontinued.

Some 10 months later, however, Edwards telephoned Dr. Tardif's office, and spoke to Dr. Ettinger, an internist who practiced with Tardif. Edwards told Dr. Ettinger that she was depressed. "Ettinger had no prior knowledge of Edwards, had never treated her, and had never discussed her condition with Dr. Tardif."[4] He "did not inquire into the details of the events precipitating Edwards' depression, nor did he ascertain how many previous bouts of depression she had suffered."[4] Based on the phone call, Dr. Ettinger prescribed 100 pills of Tofranil. Eight days later, Edwards committed suicide by overdosing on the Tofranil.

At trial, the plaintiff presented evidence that Dr. Ettinger's treatment of Edwards fell below the accepted standard of care for internists, and offered expert testimony that (a) suicide is "a known symptom and risk in individuals suffering from depression;"[4] and (b) if Dr. Ettinger had conformed to the applicable standard of care, Edwards' death "would have been prevented."[5]

The jury returned a verdict in excess of $500,000 against Dr. Ettinger and the corporation which employed him, Tardif and Ettinger, P.C. The Supreme Court affirmed the verdict.

Analysis

Traditionally, the rule has been that suicide was an act that broke the chain of causation between the claimed malpractice of the physician, and the resultant harm to the patient.

> As a general rule, negligence actions seeking damages for the suicide of another will not lie because the act of suicide is considered a deliberate, intentional and intervening act which precludes a finding that a given defendant, in fact, is responsible for the harm.... [W]here an action is brought under a wrongful death statue the general rule is that suicide constitutes an intervening force which breaks the line of causation ... and therefore the wrongful act does not render [the] defendant civilly liable.[6]

The application of that rule, however, has been limited to those cases in which the suicide was unforeseeable. Suicide will not break the chain of causation where it was the foreseeable result of the defendant's negligent act.[7]

Connecticut has long recognized that a health-care provider may be liable for the suicide of a patient in the custody of the institution, provided that the institution knew or should have known of the patient's suicidal tendency, but failed to "give him such reasonable care as his mental and physical condition required."[8] This rule applied whether the admission was voluntary or involuntary,[9] but was limited to those cases where the patient was in the custody of the provider. *Edwards*, for the first time, addresses liability which may pertain to the suicide of a noncustodial patient.

Connecticut has recently adopted the standard set forth in §442B of the Restatement (Second) of Torts. This provides that

> where the negligent conduct of the actor creates or increases the risk of a particular harm and is a substantial factor in causing that harm, the fact that the harm is brought about by the intervention of another force does not relieve the actor of liability, except where the harm is intentionally caused by a third person and is not within the scope of the risk created by the actor's conduct.[12]

The Court relied on this rule in affirming the jury's verdict. The court held that where a physician commits malpractice, which is a substantial factor in causing the patient's suicide, and where the suicide was a foreseeable consequence of the malpractice, then the physician may be liable, even though the patient was not in the custody of the physician, or any other provider.

> In our view, the circumstances in which a physician may be liable for a patient's suicide are not limited only to when the patient is in the physician's custody. Instead, the relevant inquiry is whether a defendant failed to provide reasonable treatment for the patient and that failure proximately resulted in the patient taking his or her own life.[11]

The *Edwards* decision does not mean that a physician has a duty to *prevent* the suicide of a noncustodial patient. The court rejected that possibility.

> We merely recognize that 'a cause of action may exist for professional malpractice when a [physician's or other health care provider's] treatment of a suicidal patient falls below the standard of care for the profession, thus giving rise to a traditional malpractice action....' Indeed, were we to adopt the view that a physician has a duty to prevent a patient's suicide, even though the physician's treatment has conformed to or even surpassed the appropriate standard of care, imposition of liability in those circumstances would amount to strict liability.[12]

Application of the Rule

The *Edwards* decision clearly does not impose liability upon a physician in every case where a patient commits suicide. Such liability may be imposed only where three questions are answered affirmatively: 1) Did the physician commit malpractice; that is, did the physician fail to exercise the degree of skill, care, and diligence that is customarily demonstrated by physicians in the same line of practice;[13] 2) Was the patient's suicide a foreseeable result of the physician's malpractice; and 3) Was the physician's malpractice a substantial factor in producing the suicide?

Nonetheless, the *Edwards* decision changes the medical-legal landscape. Suicide by an outpatient is no longer a bar to an action for wrongful death resulting from medical malpractice. Physicians may be held liable for the death of someone they have never met; and may be found liable even though the patient was not institutionalized or in their custody. In particular, the implications of the *Edwards* decision may have consequences for mental health practitioners treating patients under managed-care plans. If a patient expresses suicidal ideation, but the managed-care company does not agree to pay for appropriate treatment, the physician may be caught between rendering care without payment, or risking liability if anything goes wrong. If caught in this dilemma, the physician should keep careful records documenting the treatment and payment chronology, and consult with an attorney promptly.

The imposition of liability as laid out in *Edwards* is certainly fact-specific, and may occur only rarely. However, *Edwards* surely sounds a cautionary note for physicians, reminding them to exercise great care in diagnosing and treating their patients.

CITATIONS

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2. Id. at 618.
3. A brand name for imipramine, a tricyclic antidepressant.
4. *Edwards*, 240 Conn at 613.

5. *Edwards*, 240 Conn at 614
6. *Edwards*, 210 Conn at 615 (internal citations omitted).
7. See, for example, *Champagne v. United States,* 513 N.W.2d 75, 7677 (N.D. 1994): "If the patient's act of suicide is a foreseeable result of the medical provider's breach of duty to treat the patient, the patient's act of suicide cannot be deemed a superseding cause of the patient's death that breaks the chain of causation between the medical provider and the patient, which absolves the medical provider of liability."
8. *Hawthorne v. Blvthewood. Inc.,* 118 Conn. 617, 174 At. 81 (1934).
9. *Mahoney v. Lensink,* 213 Conn. 548, 569 A.2d 518 (1990); *Hawthorne v. Blythewood. Inc.,* 118 Conn. 617, 174 At. 81 (1934).
10. See *Stewart v. Federated Dept. Stores. Inc.,* 234 Conn. 597, 662 A.2d 753 (1995).
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12. Id. at 618, n. 7. (interior citations omitted).
13. Logan v. Greenwich Hospital Assn., 191 Conn. 282, 465 A.2d 294 (1983).

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From *The Connecticut State Medical Journal*
May 1948

Editorial

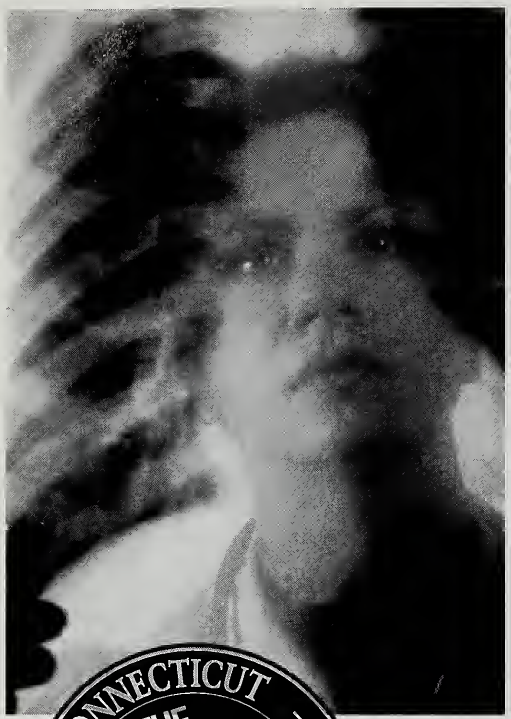
Medicine in a Planned Economy

IN a recent issue of the *British Medical Journal* (13 March 1948), under the title of "Where are we going?" Dr. Ffrangcon Roberts of Cambridge, England, has some interesting comments on Medicine in a Planned Economy. He points out the extraordinary expansion which has taken place in medicine, particularly during the last twenty years, expansion involving not only physical facilities but an expansion witnessed by the great army of physicians, nurses and such auxiliaries as radiological technicians, dietitians, laboratory technicians, physiotherapists, social workers, clinical photographers, record librarians, occupational therapists, and hospital physicists, to mention some. The existence of this course of affairs is well recognized. What is not recognized is its acceleration and, as the author points out, nothing short of a decline in population can operate as a limiting factor.

In theory it might be expected that a diminution in disease might be expected when the whole population is adequately fed, housed, clothed and educated. However, there does not seem to be much causal relationship between social conditions and most of the major diseases which fill hospitals. In addition, many unnecessary examinations, particularly in the field of radiology, are carried out through fear of litigation, examinations made not because of their clinical necessity but from fear of severe penalties. The most reasonable hope for the diminution of disease would seem to lie in the advancement of science. However, even here it is up against the inevitable, for the concern is chiefly the postponement of a natural termination, "we live in an age of increasingly medicated survival." Since we can see no sign of any arrest in this accelerating expansion, and since such expansion is incompatible with a contracting economy, it must be concluded that the limit will be determined by the available resources of manpower or cost, or both, for medicine is not above economic laws and a limited and a planned economy cannot support a health service expanding with acceleration which is now exhibited.

The author sees these dangers for his country. First, money and labor will be spent on trifling ailments to the detriment of those who are seriously ill. Secondly, individual attention and mature thought will be replaced by routine performance and responsibility beyond their capacity will be delegated to subordinates. Thirdly, the threat of freedom of action in dealings with patients will be forced on the medical profession by economic necessity. When this comes if it is at all possible it should be self-imposed by those who understand the subtleties of clinical medicine and not by those who only have a bureaucratic acquaintance with it. Dr. Roberts ends his stimulating and thoughtful remarks with these words, "We rightly dread any violation by the State of the sanctity of the doctor-patient relationship, but the preservation of this sanctity depends upon the full recognition of the doctor and patient alike that individual health and national health cannot be dissociated, and that intelligent but at the same time unselfish regard for his own health is not the least contribution which every citizen must make to national prosperity."

Reprinted from the *Connecticut State Medical Journal*, May 1948.



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THE PRESIDENT'S PAGE

Memorial Day

In the apocalyptic vision two of the scourges of mankind depict War and Death, represented by pestilence and disease. Our civilization has long experience with both. Both have proved devastating to all that we as a society prize collectively as well as individually. There is a distinction that can be drawn between the two. While war often presages pandemic disease, there are many examples over the centuries of ravaging epidemics sweeping through civilization without regard to the presence of armed conflict. The 14th century saw the waxing of bubonic plague that swept throughout the continents of Africa, Asia, and Europe leading to the death of one third to one half of the existing population of Europe before finally waning, only to return sporadically and unpredictably in the decades and centuries since.

Writing to a medically-oriented audience I only mention a few of the others: small pox, cholera, dysentery, typhoid, typhus, yellow fever, malaria, and poliomyelitis. With the exception of small pox all of these adversaries of ours have been with us generation after generation, reeking havoc on our social and economic structures and destabilizing large portions of our population. If there is ever a positive side to such unmitigated disaster I believe one could postulate a generally positive image of medicine's response to threats. As the plagues raged, there grew the tradition and ethic of physicians standing with their patients, many times woefully ignorant and powerless to cure, but standing nevertheless, learning, empowering themselves with knowledge, and finally offering effective treatment. Heroes indeed. Unknown to us in the sweep of history but represented by modern heroes. Benjamin Rush in Philadelphia with the wrong treatment for yellow fever but nevertheless standing with his patients; Walter Reed and his battles with malaria; William Gorgas and his dual with both. The tradition and ethic passes down to us today, and our generation has embraced the challenges to stand with our patients as we confront new diseases such as HIV, hemorrhagic fever, and a host of others.

War perhaps epitomizes the most awful of the scourges because of its entirely human causation. No responsible force of nature here. But again this truly horrific state of human affairs has afforded us, the physicians, an opportunity to excel in the delivery of medical care to our soldiers, sailors, and airmen, as well as the affected civilian population both allied and enemy.

It was 30 years ago this month and I was three quarters of the way through my tour of duty in Vietnam. A very eventful year. The Tet Offensive had come in February and my assignment at the 2nd MASH (Mobile Army Surgical Hospital) had resulted in days of uninterrupted surgery and nights of sporadic bombardment as the North Vietnamese Army attacked in force throughout the Republic of Vietman. It was a military victory for the U.S,. by the way, just not a political one. Reflecting on that period of time, once the dust had settled, allowed me to call into focus the significance of what had been accomplished with skill, dedication, and professionalism.

All the medical doctors assigned to the 2nd MASH were draftees. Our ranks included general medical officers, internists, general surgeons, orthopedic surgeons, anesthesiologists, a neurosurgeon, an ophthamologist, a urologist, and a radiologist. What makes all this remarkable was the single-minded dedication of the entire medical staff. Overall morale was high. There were established standards. We tried to practice to the highest level that circumstances allowed. Colleagues assigned who could not meet the standards (there were few) were requested to be transferred to less active areas of operation.

Most of the physicians had been in practice or held academic appointments for one or two years. Most had left young families stateside. Once in the country and assigned to 2nd MASH, it did not take long to establish one's priorities and obligations. Altruism was the unspoken order of the day. Tragic events allow us the opportunity to rise to meet them. This time, I remember, was such a time. It was a time for me to be associated with a number of dedicated physicians devoting their efforts entirely to the best interests of their patients and each other. The medical annals of the war, the TB Meds (Technical Bulletins, Medicine) describe the success of our endeavors. Very little of the story of medical care during the Viet Nam war has entered the public domain. Certainly this care was delivered in the main by the citizen soldiers of the various allied medical corps.

It was my privilege to serve with them. It is my opportunity to reflect on them, their courage, skill, and sacrifice. My friends and colleagues of all service branches who, in military parlance, by their actions reflect a great credit upon themselves, the United States Armed Forces Medical Corps, and the profession of medicine.

Stanley J. Keating, Jr., M.D.
President

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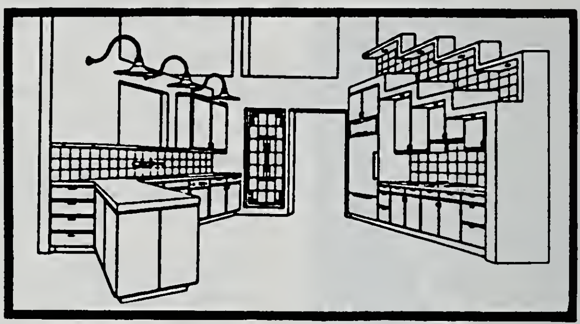

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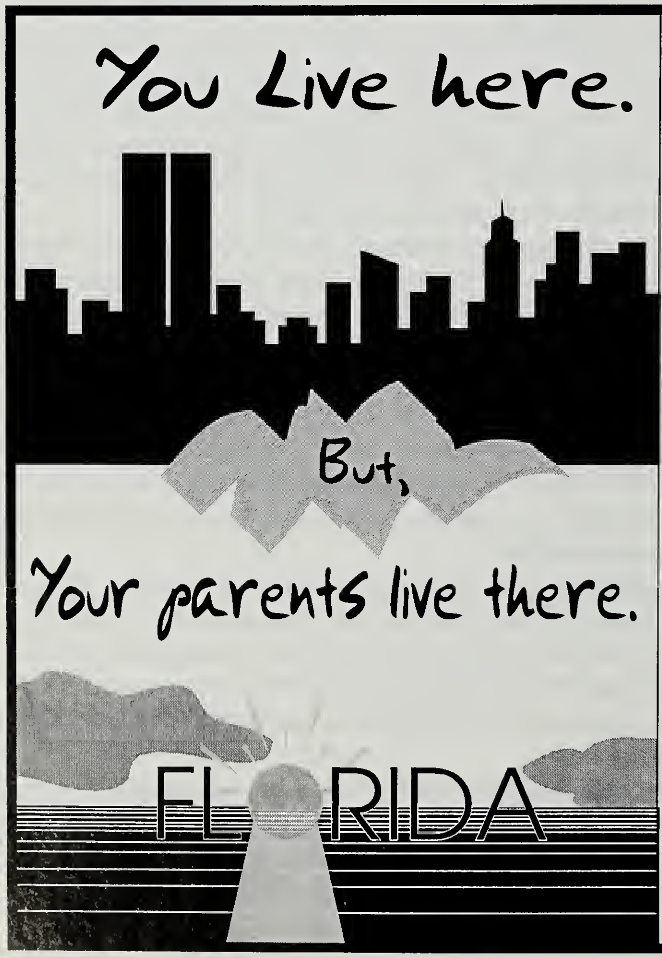
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On Words, Style, Grammar, and Other Matters

ROBERT U. MASSEY, M.D.

ONE day last month I was stopped in my tracks by two headlines in the *Hartford Courant.* The first on the front page top left:

Lobbyists
Giveth;
Legislators
Taketh

Eye-catching and true but grammatically dead wrong. The headline writer's attempt to write Elizabethan or Jacobean English failed; he had not recalled from his reading of the King James Bible or Shakespeare that the -(e)th verb ending is third person singular. But why should I assume that he had ever read either?

On an inside page I read:

Let He Who Is
Without Sin ...

He was, of course, quoting from John 8:7, "He that is without sin among you, let him first cast a stone at her," but misquoted it, even failing to recognize, actually to sense, that "he" in this instance should be "him," object of the verb "let." Minor errors that become major when printed in 18 or 30 point bold type.

Hypersensitivity to words and syntax may not be genetic but it can be acquired after a few years of copy-editing and proof-reading. My secondary editorial career began 60 years ago when I was editor of our high school newspaper, a triweekly, and later at Oberlin, as page editor on the *Review*, a semiweekly. After an interruption of over 50 years, I resumed this earlier career by accepting the editorship of both the *Journal of the History of Medicine,* and *Connecticut Medicine* , the former for only four years. As another medical journal editor once commented, "One feels like the circus horse in the barn; when the band starts to play your hooves begin to stomp." An editor reads with a pencil or a red pen in his mind, if not in his hand.

All writers commit some mortal, but mostly venial sins; either variety that shows up on the printed page is more embarrassing to the editor, or should be, than to the author. Everyone who writes needs an editor. My wife and daughter are painfully critical editors who sometimes humiliate me by laughing at something not intended to be funny. Bob Brunell scans all the page proofs along with me just before this journal goes to the printer.

Misquotations, reporting cooked data, and writing such things as "studies have shown" are mortal sins. Wrong references are almost impossible to track down, and many reviewers and most editors choose to leave the writer unredeemed, sunk in his sin. "Most studies have shown," if without references, is almost always a lie.

Politically incorrect lines here and there are venial and rarely bother me, although I have become sensitive to exclusive use of the male third-person pronoun, but equally offended by "his or her," or worse still "his/her." Leaving the subject in the singular, "a patient," and then referring to "they, their, or them," is an abomination. Example: "Everyone should have a choice of their physician." Another example appeared in the *Courant:* "Each mother, no matter her circumstances, takes an optimistic gamble on the future, whether they know it or not."

All editors have words that they rarely permit to see the light of day; mine include: most vulgarity, "impact" used to mean affect or effect or consequence, "lifestyle," "reach out or outreach," "which" instead of "that" in a defining clause, and "in the context of." Joseph Epstein, former editor of *The American Scholar,* added a few more expressions of the "reach out" psychobabble-type: "*...special, caring, and sharing,*" and I would add *healing* when the reference is not to wounds, ulcers, and fractures. Incidentally, his views of the words "gay " and "Lesbian" are the same as mine. A Lesbian is a native of the Greek isle of Lesbos, and gay, a perfectly fine word of ancient vintage (Chaucer used it) has been forever lost.

> Be comforted! Thy grief shall pass
> away.
> Art thou elated? Ah, be not too gay;
> Temper thy joy; this, too, shall pass
> away.

The world is full of books telling us how to write acceptable English. Among the classics are *A Dictionary of Modern English Usage*, by H.W. Fowler, usually referred to just as "The Fowler," and, by the same author, *The King's English.* The title dates it: first edition 1906, third edition 1931. These books are more fun to read than to use; for example:

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

> **SHALL AND WILL**
>
> It is unfortunate that the idiomatic use, while it comes by nature to Southern Englishmen (who will find most of this section superfluous), is so complicated that those who are not to the manner born can hardly acquire it; and for them the section is in danger of being useless. In apology for the length of these remarks it must be said that the short and simple directions often given are worse than useless. The observant reader soon loses faith.... (*The King's English* , p 142.)

For me *The Chicago Manual of Style* is quite adequate, and for the journal, *The American Medical Association Manual of Style* (8th ed) has served well for almost a decade. Anyone intending to write a medical article needs a copy close at hand. I have kept a "Strunk" by my typewriter, now word processor, for 35 years. *The Elements of Style* by William Strunk, Jr., was first published in 1937. Macmillan brought out a new edition in 1959 that had been somewhat revised and expanded by E.B.White (remember *Charlotte's Web*?). A professor of religion and Old Testament Hebrew asserted that E.B.White was the finest writer of English prose in the 20th century! If, by chance, you are unfamiliar with this gem, find a copy. Some examples of his straightforward style:

And/or.—A device borrowed from legal writing. It destroys the flow and goodness of a sentence.

Can.—Means *am* (*is, are*) able. Not to be used as a substitute for *may* .

Comprise.—Literally *embrace.* A zoo *comprises* mammals, reptiles, and birds, (because it embraces, or includes, them). But animals do not *comprise* (embrace) a zoo— they *constitute* a zoo.

Contact.—As a transitive verb, the word is vague and self important. Do not *contact* anybody; get in touch with him, or look him up, or phone him, or find him, or meet him.

Data.—A plural, like *phenomena* and *strata.*

Different than.—Here logic supports established usage: one thing differs *from* another, hence *different from.* Or, *other than, unlike.*

In the eighth grade I took a course called General Language in which we learned about the history of the alphabet, the history of English, including a little Anglo-Saxon, more than a smattering of French, German, and Spanish, and a second semester devoted to Latin and enough Greek to recognize ΑΒΓΔ. I recall a formal debate by six students chosen by the teacher on the topic: Can we think without words? We were then asked to write a paper, taking one side or the other; I argued that without words thinking is impossible. Now I would argue that we cannot think in the way that human beings think without language. In his prologue, the author of St. John's gospel announced this with conviction, "In the beginning was the Word." He used, of course, the Greek *logos*, which my lexicon defines as "the word by which the inward thought is expressed, or reason itself."

I suppose that since the Hundred Years War, when Anglo-Saxon and Norman French slowly fused into something recognizable as English, Chaucer's English, the aging crowd has warned that the language of those under 30 was degenerate and incomprehensible. I recall reading some lines from the 15th-century printer, William Caxton, that appeared in the prologue to his translation of the *Eneydos* (Aeneid). He was apparently copy-editing his own prose:

> ... I saw the fayr and straunge termes therein.... I doubted that it sholde not please some gentylmen whiche late blamed me, sayeng that in my translacyons I had over curyous termes whiche coude not be understande of comyn peple, & desired me to use olde and homely termes in my translacyons.

But it seems to me that something else is happening today; the language is becoming more and more imprecise. Science writing has not much suffered from this imprecision virus; in the physical and biological sciences the writers are up against verifiable reality. But in the social, psychological, and political sciences, as well as in the bureaucracies that are akin to these "sciences," such as education and management, and in the spreading crop of "studies," women studies, black studies, gender studies, obfuscation is the rule. Words or expressions such as *relate to*, *multiculturalism, diversity, validate, authenticate, value-laden, value-free, phallocentric, meaningful, significant other, disadvantaged, mentally challenged,* obscure rather than express thought, hardly the function of the *logos*. Rarely has this entered the medical literature except perhaps in the behavioral sciences and medical history or sociology. I quote an example:

> The narrative of the work is largely spatial grafting and making, moving and retaining. Given the histological basis of their analysis, this is what they see. But they also use the verbs of gift and display in the story of the rabbits.... What does the language habit tell us about the philosophy of these scientists? Are they really confused about the ontological status of their research animals, or the reality of what they are recording?[1]

If someone were to ask me to put this in my own words, I would be lost. Surely there is danger in encouraging too much of this sort of confusion in our language. Orwell's *1984* demonstrated that critical thinking can be effectively destroyed by making changes in the language that deprive it of meaning. Perhaps we need an Academy of the English Language, analogous to the Académie Français, with postmodernists and deconstructionists either excluded or in a tiny minority.

REFERENCE

1. Long DE: Moving reprints: A historian looks at sex research publications of the 1930s. *J Hist Med Allied Sci* 1990; 45: 452–68, p.462.

This Month's Reading in Review

TIMOTHY B. NORBECK

"When HMO executives make many millions of dollars in compensation, that may be okay. But when those same HMO executives complain about pennies being spent for basic consumer or patient rights, that is pure hypocrisy. The per-enrollee costs of a consumer right to appeal and many other basic protections are a fraction of the per-enrollee income made by top HMO executives."

Families USA, Executive Director, Ron Pollack,
in a press release (1 April1998)

"Eighteen out of 31 HMOs surveyed by the New York Attorney General's office 'failed more than half the time to provide consumers with copies of the plan's subscriber contract and member handbook, when asked'"... New York Attorney General, Dennis Vacco, said in announcing his intention to file lawsuits against those 18 companies, "I am seriously concerned that many HMOs are not even obeying the most basic provisions of the Managed Care Consumer Bill of Rights (which went into effect one year ago)."

Albany Times Union (7 April 1998)

"As Stan Evans noted in 'Human Events,' many HMOs operate on a capitated basis. This means that plans are paid a flat monthly fee for taking care of you. This translates to the less they spend on medical services, the more profit they make. How many markets, Mr. Speaker, function on the premise of succeeding by giving less of what they want?"

Comments by Iowa U.S. Congressman,
Greg Ganske, M.D., on the House floor and
which appeared in the *Congressional Record*
(31 March 1998)

Although the new federal parity law, which went into effect January 1, doesn't require employers to offer mental health benefits, those who do provide them can no longer set a dollar limit on treatment for mental disorders.... Moreover, Rand, a nonprofit think tank, reports that the cost of giving workers mental health benefits similar to those for physical illness is only about $1 per employer per year.

Self (April 1998)

By a 51–47 vote, the U.S. Senate voted on 1 April in favor of a "non-binding resolution" that would change portions of last year's balanced budget law to make it "easier for doctors and patients to privately contract for Medicare-covered services" ... Senators approved an amendment sponsored by Senator John Kyl (AZ), "expressing the sense of the Senate that Medicare beneficiaries should be able to see the health care provider of their choice, unlimited by 'unreasonable conditions on providers'" ... Kyl plans to bring the "actual bill to the floor soon."

Congress Daily (1 April 1998)

Dumb and Dumber: In November in Annapolis, MD, during a celebration of a man's 32nd birthday, his cousin, 21, tucked a .22 caliber handgun into the waistband of his trousers and accidentally shot himself in the groin.... As guests tried to assist him, the "birthday boy" relieved him of the gun and stuck it in the most convenient place he could find—which happened to be the waistband of his own pants.... The gun fired again, striking him in the buttocks.... Both men were hospitalized.

News of the Weird (13 April 1998)

Oxford Health Plans agreed to abide by New York regulators' directive to suspend a $9 million severance package the troubled HMO is paying its former chair Stephen Wiggins.... The New York Superintendent of Insurance Neil Levin ordered Oxford on 2 April not to give any more money to Wiggins "until regulators can ensure that the cost will not be reflected in premiums."

Hartford Courant (3 April 1998)

"When you take shareholders down from 80 to 14, one would assume you wouldn't get a tip—this is really in-your-face management."

Princeton University economist Uwe Reinhardt
commenting on the above severance package.
Newsday (3 April 1998)

Only in America: A Colorado woman was ordered to pay her estranged husband $4,000 under the state's no-fault divorce law, despite the fact that he was at the time awaiting trial for hiring someone to kill her (and for which he was later convicted and sentenced to 12 years in prison).... Under Colorado law, marital misconduct is irrelevant in a divorce, and in this case the woman happened to be earning more than her husband.

Denver Post (6 April 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

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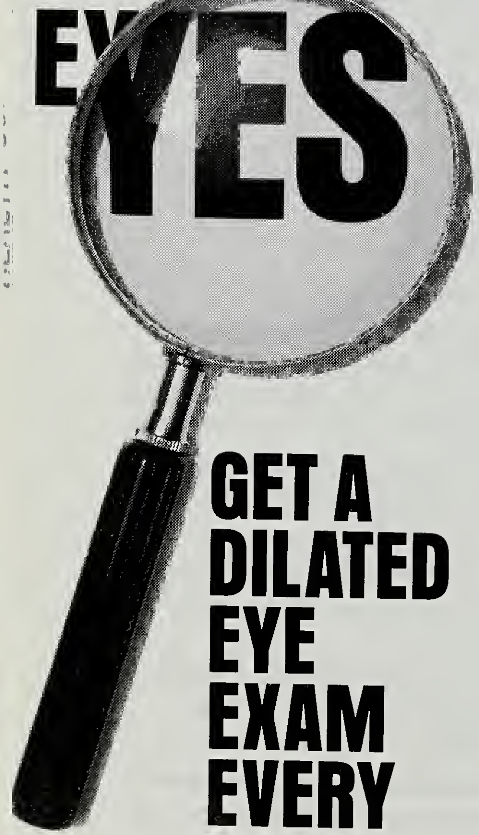
HAVE
DIABETES,
TAKE
A CLOSER
LOOK
AT YOUR
EYES



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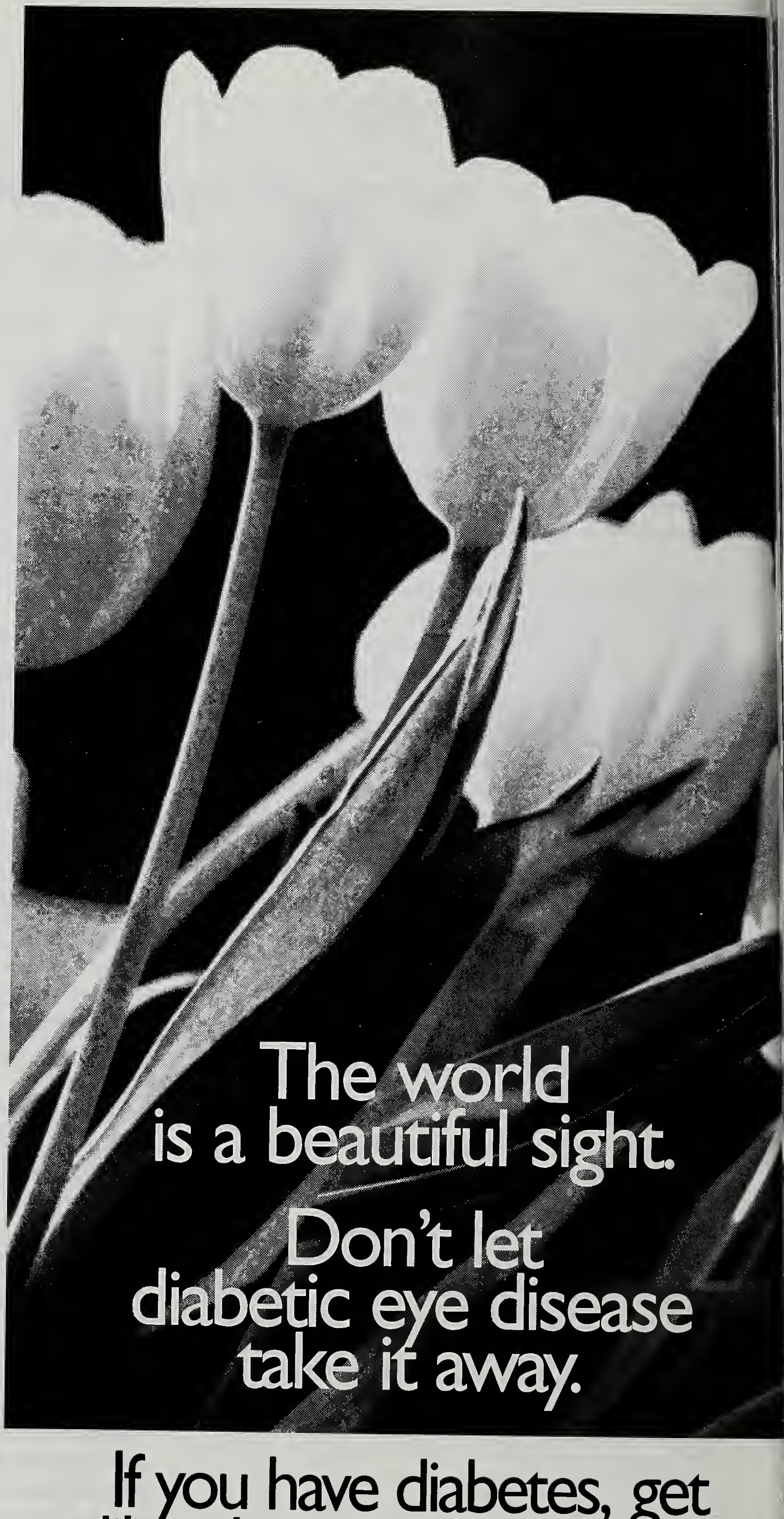

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CPRO Focus Now on Quality Improvement Collaboration

While it has been four years since the nation's peer review organizations (PROs) fundamentally changed their methodology, many practicing physicians are still not aware of this dramatic new quality improvement approach. To reflect this fact, most of these organizations now refer to themselves as Quality Improvement Organizations (QIOs) rather than PROs.

At the Connecticut Peer Review Organization (CPRO), this approach is embodied in our new vision: "Better Health Through Better Health Care Information."

Operating in this new mode, CPRO no longer performs massive amounts of individual case review. Since 1993, we have concentrated our efforts on collaborating with health care providers and community organizations in projects to improve the care received by Medicare beneficiaries. Medicare refers to this approach as the Health Care Quality Improvement Program (HCQIP).

"I have been involved with peer review and quality improvement at CPRO for more than four years," said Gary Cohen, M.D., medical director and associate clinical coordinator. "During this time I have seen the focus of PRO quality improvement change to what is clearly more collaborative work with practicing physicians in order to help achieve our common goal, improving patient care. Our HCQIP work is currently focused on profiling processes and outcomes of care for common conditions. Our goal is to affect positively the way care is delivered."

Over the past four years, these HCQIP projects have consistently demonstrated the value of working together. CPRO has been able to share lessons learned with its collaborators and analyze information for selected conditions to identify opportunities for improvement. These projects are led by physicians who serve as clinical coordinators, joined by a team of CPRO project coordinators, epidemiologists, and data analysts.

Although the initial HCQIP projects undertaken by CPRO and its partners focused on health care provided in the state's acute care hospitals, new projects are now expanding beyond the hospital walls. To keep up with the evolution of integrated delivery systems, CPRO is now conducting quality improvement projects in a wide range of settings, including physician offices, long-term care facilities, and home care. Examples of this diversity of projects and settings follow:

- Two years ago, CPRO was asked by the *Connecticut Thoracic Society* to collaborate on a project to develop an evidence-based clinical pathway for the treatment of community-acquired pneumonia. Thomas Meehan, M.D., M.P.H., CPRO's principal clinical coordinator, and Jonathan Fine, M.D., of the Connecticut Thoracic Society and Norwalk Hospital, are spearheading this 26-hospital effort. The hospitals actively participated in the planning, development, and implementation of this project, which focuses on the diagnosis and treatment of patients hospitalized with pneumonia. Interest in this project has been expressed from medical professionals in states as far away as California and North Dakota.
- The Cooperative Cardiovascular Project (CCP), a national effort to improve the care of acute myocardial infarction (AMI) patients, was piloted in four states, including Connecticut. Clinical coordinators Harlan Krumholz, M.D., and Martha Radford, M.D., continue to play key roles in this project on both a state and national level. All 32 acute care hospitals in the state are involved in this activity.
- The M.O.R.E. (Mammography Optimum Referral Effort) project involved 37 individual private practice physicians who were recruited by CPRO's clinical coordinator, Jeanette Preston, M.D. The physicians practiced in three areas of the state (Bridgeport, Windham, and the Lower Naugatuck Valley) that were identified through CPRO's Medicare data to have low rates of mammography utilization. The participating physicians agreed to counsel female Medicare patients, who came to their offices for any reason, to receive mammograms. Medicare claims data were used to track the success of this effort, which resulted in a 15.4% increase in mammography utilization.
- Physicians in private practice are being recruited to participate in a regional diabetes project led by clinical coordinators Martha Radford, M.D. and Gary Cohen, M.D. The project will promote increased adherence to accepted processes of care for diabetics.

Other ongoing CPRO quality improvement projects include treating peptic ulcer disease, stroke prevention in patients with atrial fibrillation, congestive heart failure, and many more.

And now CPRO counts a number of managed-care organizations among its new partners working toward improving health care. CPRO is currently working with a

Connecticut Medicare managed-care plan to profile preventive care services and determine barriers preventing increased utilization. CPRO is also working with the Medicaid managed care plans to develop three projects over the next two years.

In addition to these quality improvement projects, CPRO physicians and staff are also actively involved in statewide coalitions promoting mammography, influenza and pneumococcal disease immunizations, as well as beneficiary health education. These partnerships are further examples of the organization's new approach, which emphasizes improving the quality of care by improving the systems that deliver that care.

"It has been a pleasure working with the clinicians and administrative staff of Connecticut health-care institutions as we strive to achieve our vision, 'Better Health Through Better Health Care Information,'" said Dr. Meehan. Physicians and other health-care providers interested in collaborating with CPRO in the future are invited to contact Dr. Meehan at (860) 632-6330.

Future *CPRO Corner* articles will appear quarterly in *Connecticut Medicine*. The articles will feature highlights of individual HCQIP projects as well as general health care quality improvement issues.

Ken Roberts
Director of Communications
ctpro.kroberts@sdps.org

SIDEBAR: Groups that have recently formed partnerships with CPRO include:

Connecticut Chapters of Medical Specialty Societies: American College of Cardiology, American Radiology Society, American Thoracic Society.

Private and Professional Organizations: Albert B. Sabin Vaccine Foundation, American Cancer Society, American Heart Association, American Lung Association of Connecticut, Connecticut Association of Directors of Health, Connecticut Association of Not-for-profit Providers for the Aging, Connecticut Association for Home Care, Connecticut Health Information Management Association, Connecticut Hospital Association, Connecticut Nurses Association, Connecticut State Medical Society, Elderly Health Screening Service, Infectious Disease Society of America, Rhode Island Medical Society, Sickness Prevention Achieved through Regional Collaboration (SPARC), St. Francis Senior Health and Wellness Center, and VHA of Southern New England.

Academic medical centers: Beth Israel Hospital (Boston), Cedars-Sinai Health System, Los Angeles, Cal; Harvard Medical School (Boston), University of Connecticut School of Medicine and Graduate School, the University of Pittsburgh School of Medicine pneumonia patient outcomes research team (PORT), and Yale University School of Medicine and Public Health.

Connecticut State Medical Society

Seeking Editor

Robert U. Massey, M.D., editor of *Connecticut Medicine* since October 1986, has announced his intention to retire.

Requisites for being editor of the Journal are that one be a doctor of medicine and a member of the Connecticut State Medical Society, have sufficient time to do the reading and research necessary for the job, have editorial expertise, experience, and interest in discovering the latest information on various aspects of the practice of medicine.

Please submit resumes to the Executive Director, CSMS, 160 St. Ronan Street, New Haven, CT 06511.

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

Please send them to:

Robert U. Massey, M.D.
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160 St. Ronan Street
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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Regarding: "Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Review of the Connecticut State Tumor Registry"[1]

Letter to the Editor: The Connecticut Tumor Registry (CTR) was mentioned in the title of the report by Dr. Zahir et al,[1] on cancers of the soft tissue of the upper limb and shoulder in Connecticut. In recent years, the CTR has requested that reports from investigators acknowledge that: "Certain data included in this [study, report, publication, etc.] were obtained from the CTR (located in the Connecticut Department of Public Health). The author(s) assume(s) full responsibility for the analyses and interpretations of these data."

With regard to epidemiologic issues, the report on 359 cancers (ICD-O codes not specified) suggested that a real increase in the incidence of these cancers (exceeding "population growth") had occurred in Connecticut from 1950–89. Analysis of the CTR database on the 401 invasive cancers of connective, subcutaneous, and other soft tissues of upper limb and shoulder (ICD-0-2 code C491) diagnosed in Connecticut residents in 1950–89 shows that the number increased from 61 in 1950–59 to 102 in 1960–69, with slight increases thereafter (105 in 1970–79 and 133 in 1980–89). The apparent increase from 1950–59 to 1960-69 could be (at least in part) an artifact, due to improvements in completeness of cancer registration and increasing diagnostic awareness of certain cancers.[2,3] Kaposi's sarcoma[4] explains part of the increase since the late 1970s (ie, two cases in 1950–59 *vs* 15 in 1970–89). There was no apparent increase from the 1980-89 period (about 13.3 per year) to the 1990–95 period (81 cases, or about 13.5 per year). Age-specific or age-standardized incidence rates should be examined to take into account temporal changes in the age structure of the Connecticut population.

According to the article, "a significant concentration (over 70%) of the [359] patients ... resided in the central portion of the state," but "central" was not defined. The majority of the 401 cancers diagnosed in 1950–89 occurred among residents of the most populous counties (ie, 107 in Fairfield County, 98 in Hartford County, and 121 in New Haven County). The discussion section referred to "an inordinate concentration ... in patients living in the central portion of Connecticut along the Naugatuck River Valley where a large number of industrial plants are in operation." No data were presented, however, for the Naugatuck Valley region.

Occupational histories in CTR records are incomplete and should be used with caution. From a case series, "definitive statements cannot be made regarding actual relative risk" associated with occupation. A case-control epidemiologic study would be needed.

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Anthony P. Polednak, Ph.D.
Connecticut Department of Public Health, Hartford

Drs. Zahir and Dudrick respond to Dr. Polednak: In the preparation of their manuscript, the authors followed the instructions received from the Connecticut Department of Public Health prior to initiating the study more than five years ago. No mention was made in any of the correspondence in our file of the special acknowledgment of the Connecticut State Tumor Registry which Dr. Polednak quoted in his letter. However, the Connecticut State Tumor Registry is acknowledged prominently in the title of the paper, and the authors take full responsibility for the interpretation of the data, as they have with every other article, chapter, or book that they have ever written. We apologize to the Connecticut Tumor Registry for any misunderstanding on our part regarding this matter.

As stated in the introduction to the paper, the stimulus for this review was the treatment, during a short period of time, of an unusually large number of patients with upper extremity sarcomas at St. Mary's Hospital. Because the best data base available for the study and analysis of upper extremity soft tissue malignancies was the Connecticut Tumor Registry, we petitioned and received permission to conduct a 40-year review of the reported cases with the invaluable cooperation of this agency. Although the data available to us were not complete and comprehensive for each and every patient, they are nonetheless the best data available for study in the State of Connecticut. The tabulation, analysis, and interpretation of the data were accomplished as impartially as possible, despite some imperfections of the raw data in the registry. Dr. Polednak's point is well taken regarding a potential artifactual influence on the data as related to improvements in completeness of cancer registration and increasing diagnostic awareness of certain cancers throughout the past four decades. However, this is the limitation in any retrospective study of this type over that lengthy period of time. Regarding Kaposi's sarcoma, Dr. Polednak's comments are not entirely relevant in that the numbers he quotes pertain to overall incidence of Kaposi's sarcoma rather than Kaposi's sarcoma limited to the upper extremities as presented in our paper. The total number of patients with Kaposi's sarcoma involving the upper extremity for the entire 40-year period studied was 15, representing 4.2% of the total sarcomas of the upper extremities in the registry. With this small number of patients, it would be invalid statistically to examine age-specific or age-standardized incidence rates as suggested by Dr. Polednak.

Dr. Polednak is correct in pointing out that the geographic area of Connecticut referred to in the paper as "central" was not well defined. He is further correct in pointing out that the majority of the sarcomas occurred among residents of the three most populous counties. However, this is consistent with our conjecture in the paper that the geographic distribution of these patients supports an association of these tumors with industry because the highest concentrations of population in Connecticut are in industrial areas. In the discussion, the statement was made, "Because a specific history of hazardous exposure could not be ascertained in all cases, the association is only observational, and definitive statements cannot be made regarding actual relative risk with respect to these factors in this retrospective study." This addresses Dr. Polednak's statements regarding the Naugatuck Valley Region where a large number of industrial plants are in operation. Finally, we whole heartedly agree with Dr. Polednak that a case-control epidemiologic study would be needed to evaluate the data on upper extremity soft tissue malignancies in Connecticut more usefully and comprehensively. The impetus for publication of the results of our study was to present what data on this subject are available in the Connecticut Tumor Registry with the hope that it would stimulate this type of discussion and debate leading to a more thorough and scientific prospective epidemiologic investigation.

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Burdensome Medicare Guidelines

Letter to the Editor: The furor among physicians over Medicare's new evaluation and code documentation guidelines is understandable. Even legislators are concerned.[1] The guidelines are unreasonable, burdensome, and too complicated for most physicians to comply with. Physicians' workdays already have too many interruptions, too many distractions, and too little time. Adding another hassle makes no sense at all. It only demonstrates the lack of understanding between physicians and Medicare administrators. Medicare assumes that physicians take advantage of its fee schedule; but the great majority of physicians do not. They practice as honorably and cost-effectively as possible.

The confusion caused by the guidelines should not surprise us. They are a reflection of the awkward classification of office visits that resulted from the resource-based relative value system (RBRVS). For example, stratifying office visits into five different levels—brief, problem focused, expanded problem focused, detailed, and comprehensive is impractical and any system designed to document them must be equally impractical.

Confusion over fee schedules between physicians and Medicare would be minimized if offfice visit levels were reduced from five to three. Stratification into low, medium, and high levels, is not only easier but more natural. Besides narrowing the choices to a smaller number, it eliminates the uncertainty caused by trying to differentiate between imprecise terms like "expanded problem focused," and "detailed." For instance, "expanded problem focused" though it suggests a more complex level of care than "detailed," really is a simpler one.

For those visits that are time consuming or complex, physicians could provide special "explanations." Since this would clarify why a visit was billed at a higher level including "detailed" and "comprehensive," Medicare directors should be pleased.

Fraud and abuse are serious transgressions and controlling them is important. But only a small portion of physicians abuse Medicare's reimbursement system willfully. Imposing on all doctors an impractical system that perplexes more than it helps is wrong, and no amount of bureaucratic rationalization will ever make it right. Making physicians' work days more demanding takes away from time that could be spent with patients. Ultimately it detracts from their care. Instead, Medicare should devise methods to identify those physicians whose billing appears inappropriate or excessive. If conscious disregard is demonstrated then penalties are in order. But if honest errors exist then remedial reminders should suffice. Surely this is a simpler and fairer method of dealing with physicians who have misused the coding system inadvertently or purposely.

Another strategy that could help Medicare control expenditures fairly is reform of our medical tort laws. Indeed, physicians' fear of malpractice is a significant contributor to the high cost of health care. Several organizations have studied how much defensive medicine increases the costs of health care. Estimates are as high as $52 billion annually.[2] Defensive medicine has created a paradox that undermines doctors' integrity while it enhances their incomes. For example, "covering oneself" by increasing patients' follow-up visits, encouraging visits to specialists, and ordering unnecessary laboratory and imaging studies are all activities that increase physicians' incomes. Isn't something drastically wrong in a system of health care that rewards physicians for practicing inappropriately?

The Inspector General of the U.S. Department of Health and Human Services reported that about 14% of Medicare claims totalling some $23 billion could be ascribed to fraud and abuse and lack of proper medical documentation of claims.[3]

Assuming that fraud and abuse and defensive medicine are at least equally responsible for raising health-care cost, why does Medicare pay so much attention to one and so little to the other?

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Leg Edema Secondary to Bladder Distention

Letter to the Editor: We would like to report a patient similar to the patient of Sudhakar et al, (*Conn Med* 1997: 61:459-60) illustrating the occurrence of unilateral leg edema secondary to a distended urinary bladder. Our patient is unique in that a common medical condition, diabetes mellitus with autonomic neuropathy, was the underlying problem.

Case Report

E.N. is a 66-year-old woman with a history of type 2 diabetes for 10 years, who presented with a two-week history of left leg edema. She had experienced two episodes of cystitis and intermittent stress incontinence over the past six months. Her physical examination was unremarkable except for moderate pitting edema of the left leg up to the knee, with mild tenderness in the left calf. A Doppler study was negative for deep vein thrombosis. Her renal function was normal. The edema worsened in spite of treatment with furosemide. One week later, a repeat Doppler study of the leg, including the pelvic veins, showed a markedly distended urinary bladder compressing the left iliac veins as well as severe bilateral hydronephrosis. The edema disappeared within a day of bladder drainage. Her postvoid residual urine volume was 2.5 L. A cystoscopic examination revealed no anatomic obstruction. The cause of her urinary retention was thought to be autonomic neuropathy, secondary to her long-standing diabetes.

Diabetic autonomic neuropathy often presents with urinary retention and overflow incontinence. Our patient's atypical presentation of this common problem may actually occur more frequently than the literature suggests.[1,2] We urge that venous obstruction be considered early in the differential diagnosis of edema, especially in patients with urinary symptoms and diabetes mellitus.

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From the Executive Director's Office

COUNCIL MEETING

Wednesday, 18 March 1998

Attendance

Present, in addition to the chairman, Dr. Joseph Sadowski, were Drs. Ahamed, Bigos, Beck, Bobruff, J. Czarsty, Deren, Eslami, Handelman, Herzog, Katz, Keating, Lesnik, Schwartz, Timmerman, Van Linda, and Wetstone.

Also present were: Mr. Norbeck, Ms. Lindquist, Mr. Brunell, Ms. Morelli, Ms. Norbeck, Ms. Schaffman (all CSMS staff), Mr. Thompson, (FCMA staff), Mr. A. Schuman (NLCMA staff), Mr. Fiorentino, (HCMA staff), and Dr. Genel.

Absent were: Drs. Brooks, C. Czarsty, Fischbein, Franklin, Geary, Maloney, Montegut, Mushlin, Narayanan, Redmond, Scarpa, Sindwani, Sosa, Tesoro, Watson, Wesler, Wolfson, and Zeppieri.

Reports of Related Organizations

M. D. Advantage: Dr. Michael Deren, Chair of the Board of M.D. Advantage, reported that Mr. James Darnell was no longer affiliated with M.D. Advantage and expressed his appreciation to him for getting CSMS started in this venture. He reported that Attorney Greg Pepe is now the CEO of M.D. Advantage. He is a principle in the corporation of Neubert, Pepe and Monteith, PC., located in New Haven, specializing in health-care business and is knowledgeable in integrating physicans' practices. He introduced Sandra DeRosa who was appointed Physicians' Services Director of Marketing and Regional Development of M.D. Advantage. She is part owner of a company called North Star Health Advisors located in Connecticut and specializes in physician integration and managed care. He also announced that William Greenfield from Dallas is going to be the acting CEO for the MSO. He has 11 years of experience working as a senior consultant for various firms. All questions may be directed to M.D. Advantage and hopefully a response will be made on the same day. The business plan is still in the draft stages and the marketing plan is also being worked on.

CSMS-IPA: Drs. Jeffrey A. Hertz, Mahmoud Okasha, and Guy VanSyckle, all members of the CSMS-IPA Board of Directors, joined the Council and made presentations about the activities of the organization and made reference to the resolution concerning the limitation of the terms that the directors may serve. Dr. David Thompson, president of the CSMS-IPA also submitted a written report to the Council outlining the functions and activities of the Corporation.

At the last meeting of the Council, it was VOTED to table the following resolution:

"Resolved, that the shareholder hereby consents to the 3 September 1996 adoption of an amendment to the bylaws of the corporation under Article IV, Section 3, to eliminate the limitation on the number of terms that a director of the corporation may serve."

Following the presentations and discussion, It was VOTED to take the resolution off the table and to approve the resolution.

Report of the President

Dr. Keating reported on a meeting that he had with Dr. Vincent Catrini, Chief Medical Officer of M.D. Health Plan, which also included Drs. Deren, Timmerman, and Mr. Norbeck. The purpose of the meeting was to express concern about allegations being made about the relationship between CSMS-IPA and M.D. Health Plan. Dr. Catrini assured the group that there was no intent by Foundation Health Systems to abrogate the relationship that existed between the CSMS-IPA and the merged HMO that will come into being at some point in the near future. He did not rule out that there may be a name change and that the license that they continue to operate under might be other than M.D. Health Plan.

He reported that efforts have continued to develop a relationship with the Board of Medical Examiners and he had a meeting with Richard Ratzan, M.D., chairman of the Medical Examining Board. Several avenues of cooperation were discussed with the expectation that future meetings will occur after the current legislative session. CSMS is allowed to submit names of candidates to the Medical Examining Board.

It was also reported that the CSMS relationship with the State Department of Health continues to grow and there have been discussions on a variety of issues. He stated that he was impressed that the Commissioner has made himself readily available to staff and members of CSMS.

He stated that he attended the AMA Leadership Conference in Washington and felt it was an outstanding session and that the general atmosphere and tenor of the meeting was upbeat and not negative in any way and that the breakout sessions were all well done. He mentioned that President Clinton, General Colin Powell, and several prominent legislators addressed the group.

A portion of the conference time was devoted to the issue of the Documentation Guidelines for Evaluation and Management Services that HCFA is imposing on CPT codes and billing. This has caused considerable concern among the physician community. The CSMS Committee on Medicare has issued, at the call of the AMA, suggestions for guidelines as to how the E &M codes should be changed. A copy of these suggestions will be distributed to members of the Council, and Dr. Steven Levinson, a member of the CSMS Medicare Committee, will be going to Chicago to represent CSMS on this issue. (Dr. Levinson's report appears in this issue.)

The Committee on Public Affairs has resolved the issues that arose between the osteopaths and the M.D.s regarding the advertising campaign on "M.D. Makes the Difference" and hopefully we will go forward with what will be an elaborate and effective campaign. Dr. Beck will report on the financing of this program.

This was Dr. Keating's final report to the Council as president and he expressed his thanks to the Council members.

Report of the Executive Director

Mr. Norbeck reported on the following items:

It was reported that there was much discussion in the media over President Clinton's Patient's Bill of Rights proposal and Representative Norwood's PARCA bill (The Patient Access to Responsible Care Act). The AMA supports many of the patient-friendly issues in the president's proposal, giving patients more choice, better access, and more information, but hasn't officially endorsed it. Unfortunately the president's bill did not address the ERISA problem.

The Norwood legislation, in addition to requiring health plans to establish grievance and appeals procedures, ban gag clauses and cover emergency services based on a prudent layperson's standard, it would amend ERISA to end health plans and self-funded employer's protection from malpractice suits. The AMA supports almost all of the Norwood bill, especially the ERISA provision. The AMA supports legislation that would remove ERISA preemption provision on courses of action against all managed care plan administrators to recover damages for personal and financial injury or wrongful death. The only recovery permitted now, without removing the ERISA preemption, is the value of lost medical benefits.

Despite the many good provisions, it was reported that there is something amiss in the Norwood legislation that prevents AMA from signing off on it until some of the issues questioned and suggestions made by the AMA have been resolved.

HMO physician choice has become a huge campaign issue in Texas. Ninety-five percent of Texas Democrats voting in the last primary approved a resolution calling on the party to push for legislation allowing physician choice for persons enrolled in managed-care plans.

He reported that the U.S. Chamber of Commerce was launching a multimillion dollar advertising campaign against the trial lawyers in order to promote tort reform.

Mr. Norbeck reported that hehad spoken at a senior citizen meeting in Meriden on Medicare and the legislative changes, and all were concerned about having their choice of physician. In fact they were adamant about it.

Legislative Update

Dr. David Parke, Chair of the Legislative Committee, expressed his appreciation to all the physicians who testified and made telephone calls on the various issues. The telephone call response on the APRN issue was astounding not only to CSMS but also to the legislators. He reported that the APRN Bill was dead for the session, with a 15 to 9 vote in committee, mainly because they were voting on the same bill as was presented at the last legislative session.

Dr. Parke reported on other bills that CSMS has been following this session:

- The physician profiling bill was voted out of Human Services Committee. CSMS needs to have the bill amended with substitute language developed according to the guidelines established by the CSMS Ad Hoc Committee on Profiling.
- The CSMS attempt to pass Senate Bill 508, a bill to require prompt managed-care payments has died in the Insurance Committee. CSMS effort was thwarted by the House Leadership's moratorium on managed-care legislation.
- Bills in both the Public Health Committee and the Insurance Committee regarding Managed Care Liability have been lost due to the managed-care legislative moratorium.
- CSMS efforts to have a bill raised banning discrimination of board certified physicians was unsuccessful due to the moratorium, but CSMS received assurance that the issue would be revisited next session. CSMS was directed by the House of Delegates to pursue this legislation.
- CSMS has serious concerns with the language of a health-care fraud bill in the Judiciary Committee that was proposed by the Attorney General. CSMS legal counsel is working on the proposal.
- The Labor Committee voted out a bill placing some managed-care reforms in workers' compensation medical plans and CSMS is supporting that bill.
- There is a proposal to regulate provider sponsored organizations that CSMS is supporting and following closely.

A detailed list of other issues, as well as the AMA's federal talking points, was distributed to the Council members.

Following Dr. Parke's report, Dr. Stephen Katz brought to the attention of the Council that two federal agencies were becoming involved in the scope of practice of allied health professionals and expressed his concern that any decisions regarding all professional licensure be made at the state level, and not be usurped by federal legislation or rule-making. It was VOTED that Dr. Katz would supply the Committee on Legislation with supporting material on this issue.

Report of Subcommittee on Preliminary Study of Nominations

With minor amendments, it was VOTED to approve the report of the Subcommittee and to transmit the slate of nominees to the House of Delegates for election with the Council's recommendation for approval. In approving the report, the following changes were approved.

a) Disband the Committee on Data Study.

b) Disband the Committee on Statewide Medical Planning.

It was VOTED that in the future, the Nominating Committee be supplied with a biographical sketch for those members who are to be nominated to the CSMS-IPA Board.

Mental Health Committee of CSMS-IPA

A communication was received from M.S. Okasha, M.D. who is chair of the Mental Health Liaison Committee of the CSMS-IPA and M. D. Health Plan. The committee is composed of 12 members representing the county associations, specialty groups, and CSMS. Dr. Theodore Zanker, the CSMS representative has resigned from the committee and Dr. Okasha is requesting a replacement for Dr. Zanker to represent CSMS. It was VOTED to nominate Boris Rifkin, M.D., New Haven to serve on the committee.

Connecticut Medical Insurance Company

In accordance with Council action, prior to each annual meeting of the House of Delegates, a report is presented from CMIC. Dr. Sultan Ahamed, president and chair of the Board of CMIC, reported as follows: 1997 was a challenging year for CMIC because of increased competition by out-of-state insurers engaged in aggressive pricing and marketing tactics. Ironically, these companies were organized and sponsored by neighboring state medical societies. It was reported that over 91% of CMIC physician policyholders renewed their insurance with CMIC and, while some competitors may produce limited success, the long-term implications for physicians insured by these companies was not good. It was noted that, recently, PIE Mutual Insurance Company was placed in liquidation by the Ohio Department of Insurance, that left 15,000 physician policyholders in 10 states without coverage, and PIE is not paying or settling any outstanding claims.

Closer to home, CNA has announced that it will not be renewing its physician professional liability insurance policies in 1998. CMIC will be working in the interest of Connecticut physicians to ease the transition for those who will be seeking insurance this year. CMIC will maintain its underwriting criteria for all new applicants.

CMIC has moved forward in response to the needs of expanding integrated group practices and the identified need for coverage by other health-care professionals, such as dentists, oral surgeons, dental hygienists, and APRNS. Also there will be expanded coverage for business owners for medical office practices through partnerships with A.M. Best rated insurance companies.

CMIC's leadership and professional staff recognize that the delivery of quality member services is critical to setting CMIC apart from the competition. Therefore, the delivery of a spectrum of products and services of unsurpassed quality is at the heart of CMIC's commitment to channel all of its resources to its members.

Report on Pension Fund

In accordance with Council action, prior to each House of Delegates meeting, a report is given on the Pension Fund. Dr. Roger Beck reported that the Pension Fund is fully funded, prudently invested, and all necessary reports have been filed.

CMIC Board of Directors

A communication was received from CMIC informing CSMS of the physicians to be nominated as directors at the CMIC Annual Meeting on 13 May 1998. They are: Sultan Ahamed, M.D., *Norwich,* Dennis Huskins, M.D., *Norwalk,* Stanley J. Keating, Jr., M.D., *Hartford,* Vazrick Mansourian, M.D., *New Haven,* and David R. McKee, M.D., *Stamford.* It was received as information.

COMPAC

Dr. Donald Timmerman, chair of COMPAC, reported that COMPAC is more than funds for elections. He stated that COMPAC is a lot of the things that have been discussed today in terms of exposure, advocacy, and education of legislators regarding the issues facing medicine toaday. He reported on statistics of COMPAC membership and expressed disappointment with the numbers.

Date of Future Meeting

Council Meeting—Thursday, 25 June 1998

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 JUNE 1998 NUMBER 6

scientific:

Garry Lapidus, Trudy Lerer, Robert Zavoski, and Leonard Banco 323 **Childhood Injury in Connecticut**

Marcia Trapé 333 **Workplace Violence: Occupational Safety and Health Administration Guidelines for Workers in Health Care and Social Services**

Arthur O. Pinney, Jr. and W. David Hager 337 **Teaching Senior Medical Students in an Office Setting: The Apprentice System Revisited: A Cardiologist's Perspective**

Morbidity and Mortality Weekly Report
343 **Mortality Among Children with Sickle Cell Disease Identified by Newborn Screening During 1990-1994—California, Illinois, and New York**

The Medical Letter
347 **Toremifene and Letrozole for Advanced Breast cancer**

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special articles:

NOT IN CIRC

Maureen Malloy D'Honau 349 **'On Machine': His Doctors Avoided the Dying Patient's Agony**

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668
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commentary:

Ann Merriol Almond 353 **"A Close Look at Therapeutic Touch"**

departments:

Fifty Years Ago
355 **Experience is the Best Teacher**

The President's Page
Craig W. Czarty 359 **The Challenge of Change**

Reflections on Medicine
Robert U. Massey 363 **Neutrinos, the Mind, and the Theory of Everything**

Medical News Capsules
Timothy B. Norbeck 365 **This Month's Reading in Review**

Letters to the Editor
Stephen R. Katz 366 **"All Politics Is Local"**
Charles W. Needham 366 **In Response to Dr. Bentivegna's Commentary**
The Need for Single-Payer Catastrophic Health Insurance
Henry N. Blansfield 367 **The Ethics of Organ Transplantation**

From the Executive Director's Office
CSMS 368 **Annual Meeting of the House of Delegates**
375 **Address of the Executive Director**
379 **Address of the Retiring President**

general:

381 **In Memoriam**
383 **CSMS Physician Placement Service**

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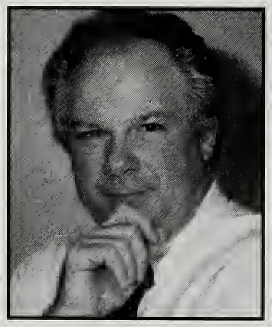

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Childhood Injury in Connecticut

GARRY LAPIDUS, PA-C, M.P.H., TRUDY LERER, M.S., ROBERT ZAVOSKI, M.D.,
AND LEONARD BANCO, M.D.

ABSTRACT—We reviewed vital statistics (1988–95) and hospital discharge data (1990–94) for Connecticut children and youth to describe the epidemiology of childhood injuries. There are approximately 175 deaths (rate=21/100,000) and 4,230 hospitalizations (rate=468/100,000) annually due to injury. Nonfatal injuries resulted in over 94,000 hospital days at a cost of nearly $155 million dollars. Death and hospitalization rates are highest among male children and adolescents 15 to 19 years of age. Geographic analysis of injury revealed significantly higher injury death and hospitalization rates in towns greater than 100,000 population. In addition, a majority of the homicides occurred in large urban areas, and most of the motor vehicle occupant deaths and suicides occurred in suburban and rural areas.

Injury is an important cause of mortality and morbidity in youth and is largely preventable. The data presented here allow for the development, implementation, and evaluation of community based injury prevention programs.

Introduction

ACUTE injury is an age-old problem, but it remains the leading cause of death and disability for United States children and youth.[1,2] These include both unintentional injuries (motor vehicle related, falls, burns, poisoning, drowning) and violence (assault, homicide, suicide). In 1995 over 20,000 American children and youth under 20 years of age died from injuries resulting in an annual age specific death rate of 29 per 100,000 population. At the national level, injury greatly surpasses all major disease groups as a cause of years of potential life lost because it is the preeminent cause of death among children and young adults. More years of future work life are lost to injury each year than to heart disease and cancer combined.[1,2] Nonfatal injuries are also a common cause of hospitalizations and emergency department treatment, and the financial costs are staggering: injuries cost billions of dollars in health care and social support resources.[3]

Injury control has come a long way in the 12 years since the publication of *Injury in America.*[4] Many of the far-sighted recommendations of that publication have been implemented. Injuries can be prevented by changing behaviors through education, by changing laws or regulations, and by changing products and the environment to improve safety. However, injury has not received the same level of public and professional attention and resources as have other health issues. Despite recent progress, injury remains a major public health problem.[4] In this

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study we describe the epidemiology of childhood injury in Connecticut, and recommend prevention approaches to avert and reduce the burden of injury.

Methods

Demographic data on fatal injuries from 1988-95 were obtained for Connecticut residents under 20 years of age from Connecticut State Death Certificates, and for U.S. residents from the National Center for Health Statistics, using external cause of injury codes (E-codes) in the International Classification of Disease System, Ninth Revision (ICD-9-CM).[5] Injury was defined as any event whose primary cause of death was coded between E800 - E999. Medical misadventure and postoperative complications (E870-E879) and drugs, medicinal, and biological substances causing adverse effects in therapeutic use (E930-E949), were excluded from the analysis of injury by cause. Injury rates by age, sex, cause, and town size (>100,000, 50-100,000, 25-50,000, <25,000) were calculated.

Hospital discharge data (1990-94) for Connecticut residents under 20 years of age admitted to Connecticut hospitals were obtained from the Connecticut Health Information Management and Exchange (CHIME), the statewide database of the Uniform Hospital Discharge Data Set (UHDDS). Information abstracted from this database included primary and secondary diagnoses, as well as age, sex, length of stay, hospital charges, and patient disposition. Hospitalizations for pregnancy and birth (ICD-9-CM codes 630-679) were excluded. Deaths occurring in the hospital (n=758)were also excluded from the analysis to preclude double counting. Injuries were identified by an ICD-9-CM primary diagnosis code between 800-999. Patients with E-codes E870–E879 (medical misadventure and postoperative complications) and E930–E949 (adverse effects) were excluded from the cause specific analysis of injuries.

Connecticut's acute-care hospitals assigned E-codes to 73.8% of all nonfatal injury discharges; no adjustment was made to compensate for the 26.2% underreporting of injuries. The percentage of injury discharges with an assigned E-code increased from 66.1% in 1990 to more than 90.3% in 1994. This was due to legislation passed in 1993 mandating the use of E-codes in injury-related discharges.

Connecticut 1990 population data were used to calculate annualized age- and sex-specific death and hospitalization rates per 100,000 persons.[6]

Results

A. Injuries in relation to other problems.—MORTALITY: Between 1988-95, there were 5,350 deaths from all causes among Connecticut residents under 20 years of age. This results in approximately 670 deaths per year and an annual age specific death rate of 79.4 per 100,000 persons.

Overall, injury accounts for 26% of all deaths (79,427 years of potential life lost) and an annual age-specific death rate of 20.8 per 100,000 persons. Among infants less than one year, perinatal conditions (54%), congenital

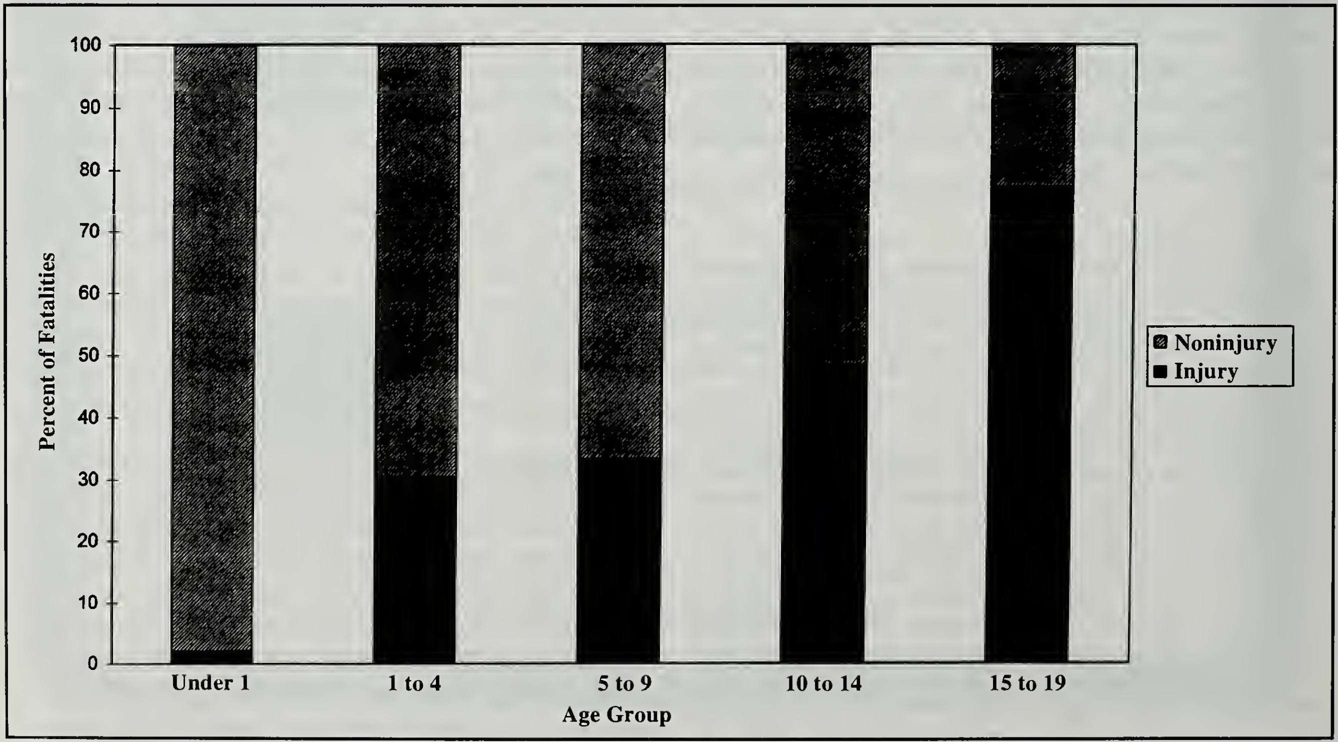

Figure 1.—Injury and noninjury fatalities by age grop, 0 to 19 years, Connecticut, 1988 to 1995.

anomalies (21%), and sudden infant death syndrome (7%) all outrank injuries, which account for just 2% of all infant deaths. However, among persons one to 19 years of age, injury is the leading cause of death, accounting for 58% of fatalities, with deaths due to cancer (9%), circulatory diseases (6%), and congenital anomalies (5%) the next most common causes.

The proportion of deaths attributable to injury increased with increasing age. Among infants less than one year, 2% of all deaths were injury related; among children one to four years, 30%; five to nine years 33%; 10 to 14 years, 48%; and among adolescents 15 to 19 years, 77% (Fig. 1).

Morbidity: When compared to other disease groups as a cause of hospitalization, injury (17%) ranks only behind respiratory diseases (19%) in frequency but ahead of digestive disorders (11%), mental health disorders (10%), ill-defined conditions (7%), and infectious disease (6%). Like the mortality data, the proportion of hospitalizations attributable to injury did vary by age but not nearly on the same scale. Among infants less than one year, 4% of all hospitalizations were injury related; among children aged one to four years, 16%; five to nine years 20%; 10 to 14 years, 20%; and among adolescents 15 to 19 years, 25%.

A total of 21,148 hospitalizations during 1990–94 were for nonfatal injuries, including 421 for "adverse effects." This averages 4,230 per year and an average annual injury hospitalization rate of 502 per 100,000 persons. The median length of stay was two days; 75% of these injury patients were discharged within four days and 85% within one week.

B. *The incidence and causes of childhood injury in Connecticut.*—The risk of injury by age and sex: Injury deaths vary in a nonlinear fashion by age (Fig. 2) with highest rates among infants, (20 per 100,000) and older adolescents (55). Except for infants where there was no difference by gender, males consistently demonstrated an injury death rate 1.5 to 4 times higher than females, with the greatest differential occurring among 15 to 19 year olds (86 *vs* 22).

Injury hospitalization rates by age and sex demonstrated a similar pattern. Rates were highest among 15 to 19 year-old males (982 per 100,000) and almost twice the female rate (539 per 100,000) for the same age group.

Causes of injury mortality and morbidity: Overall, 65% of injury deaths were due to unintentional causes, with remaining deaths due to homicide (23%), suicide (11%), and unknown intent (1%). Guns were used in 77% of homicides and 52% of suicides. Other leading methods of suicide were suffocation (29%) and poisoning (14%). Among nonfatal injuries, most were due to unintentional causes (83%), followed by self-inflicted (10%), assault (6%), and unknown causes (1%).

Table 1 compares the leading causes of injury-related deaths and hospitalizations by age group. Overall, falls were the leading cause of injury hospitalization, account-

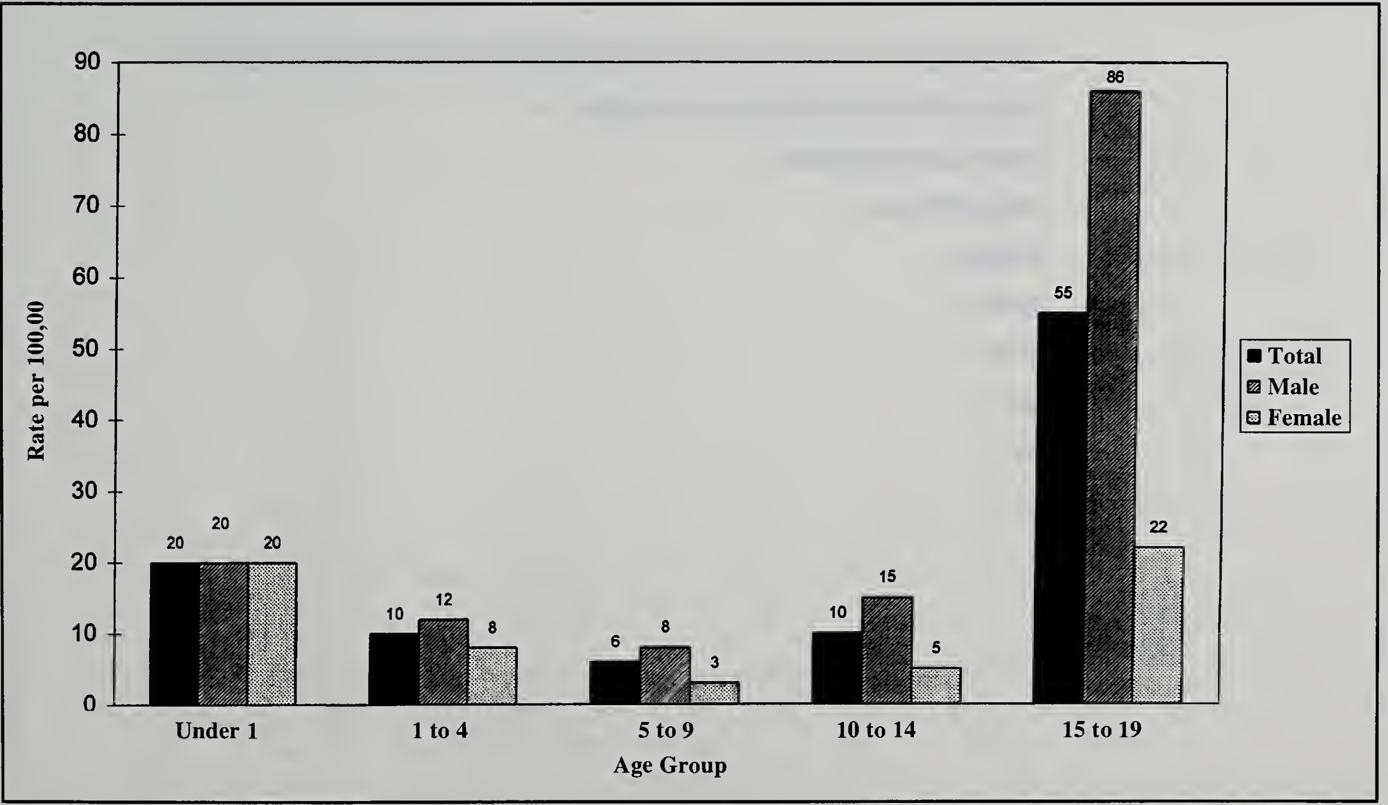

Figure 2.—Fatal injury rate by age and gender, 0 to 19 years, Connecticut 1988 to 1995.

Table 1.—Injury Morbidity vs Mortality by Cause and Age, Connecticut

Age (years)	Cause	Hospitalizations* No.	Percent	Cause	Deaths** No.	Percent
<1	Fall	298	44.3	Homicide	19	30.2
	Fire/burn	107	15.9	Suffocation	18	28.6
	Poisoning	49	7.3	Fire/burn	5	7.9
1-4	Poisoning	991	32.7	Fire/burns	29	19.1
	Fall	837	27.6	Pedestrian	25	16.4
	Fire/burn	373	12.3	Drowning	25	16.4
5-9	Fall	989	42.1	Pedestrian	26	26.8
	Bicycle	230	9.8	Occupant	14	14.4
	Pedestrian	229	9.7	Drowning	13	13.4
10-14	Fall	874	28.1	Pedestrian	25	15.4
	Bicycle	391	12.6	Homicide	21	13.0
	Self-inflicted	328	10.5	Suicide	20	12.3
15-19	Occupant	1,318	21.9	Occupant	260	28.0
	Self-inflicted	1,129	18.8	Homicide	245	26.4
	Assault	725	12.1	Suicide	135	14.5
Total	Fall	3,631	23.9	Homicide	322	23.0
	Occupant	1,723	11.3	Occupant	312	22.2
	Self-inflicted	1,469	9.7	Suicide	155	11.0

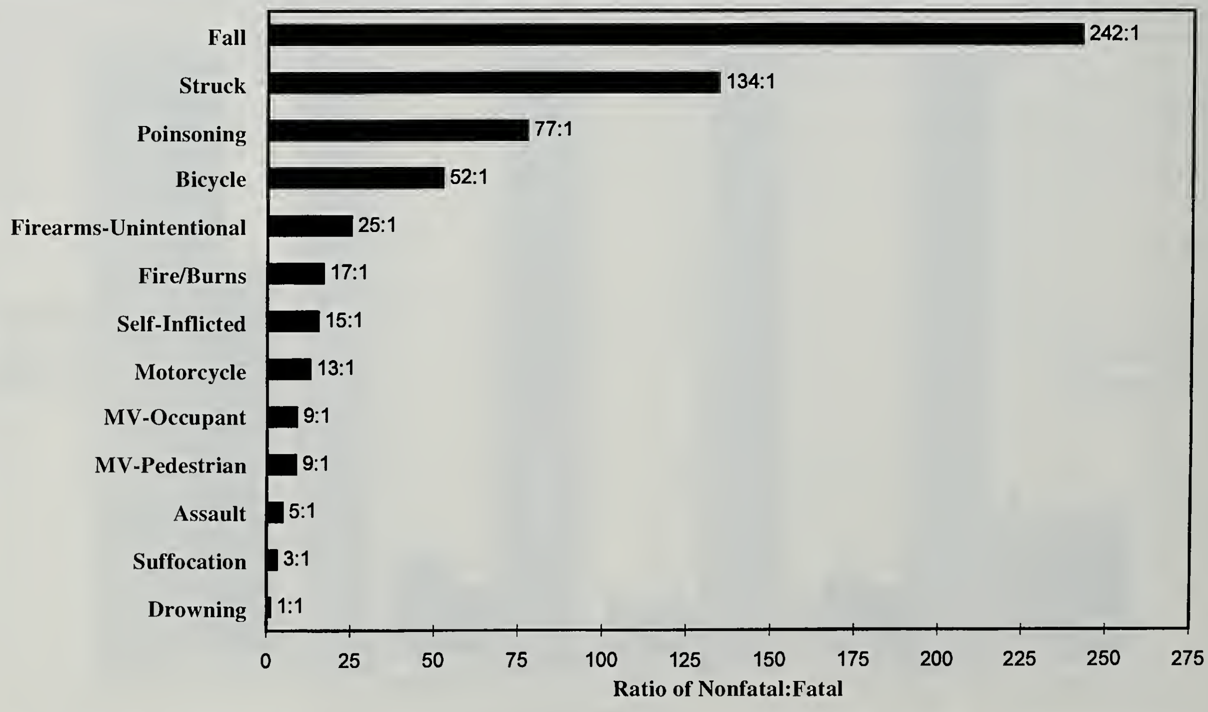

Figure 3.—Ratio of average annual nonfatal hospitalized injuries, 1990–94, to average annual fatal injuries, 1988–95, 0 to 19 years, Connecticut

Table 2.—Injury Rates by Town Size, Ages 0 to 19 Years, Connecticut

Town size*	Population <20 yrs	No. injury deaths	Injury death rate	95% CI (±)	No. injury hosp.	Injury hosp. rate	95% CI (±)
<25,000	316,926	467	18.4	4.7	6,516	411.2	22.3
25–50,000	181,330	230	15.9	5.8	3,931	433.6	30.3
50–100,000	169,797	229	16.9	6.2	4,009	472.2	32.7
>100,000	175,260	477	34	8.6	6,692	763.7	40.9
Total	843,313	1,403	20.8	3.1	21,148	501.6	15.1

>100,000:	Bridgeport, Hartford, New Haven, Stamford, Waterbury
50-100,000:	Bristol, Danbury, East Hartford, Fairfield, Greenwich, Hamden, Manchester, Meriden, New Britain, Norwalk, West Hartford, West Haven
25-50,000:	Branford, Cheshire, East Haven, Enfield, Glastonbury, Groton, Middletown, Milford, Naugatuck, Newington, New London, Norwich, Shelton, Southington, Stratford, Torrington, Trumbull, Vernon, Wallingford, Wethersfield, Windsor
<25,000	All other towns

ing for 24% of discharges, whereas homicide was the leading cause of mortality, accounting for 23% of all deaths. Motor vehicle occupant (11%) and self inflicted injury (10%) ranked second and third, respectively, as causes of injury hospitalization compared to occupant (22%) and suicide (11%) as causes of death.

When viewed by specific age group, falls were the leading or the second most frequent cause of hospitalization for all age groups, except adolescents 15 to 19 years, where motor vehicle occupant (22%), self-inflicted (19%), and assault (12%) predominated. Homicide (30%) ranked first as a cause of death among infants and ranked second among 10 to 14 and 15 to 19 year olds (13% and 26%). Pedestrian injury ranked as an important cause of death among children from one to 14 years old. Motor vehicle occupant injury, homicide, and suicide were the leading causes of death among older adolescents.

For every child fatally injured, there are more who are hospitalized with nonfatal injuries. The ratio of nonfatal to fatal injuries (ie, the case fatality rate) varies by specific cause (Fig. 3). The highest case fatality rate occurred for drownings (1:1) and the lowest for falls (242:1).

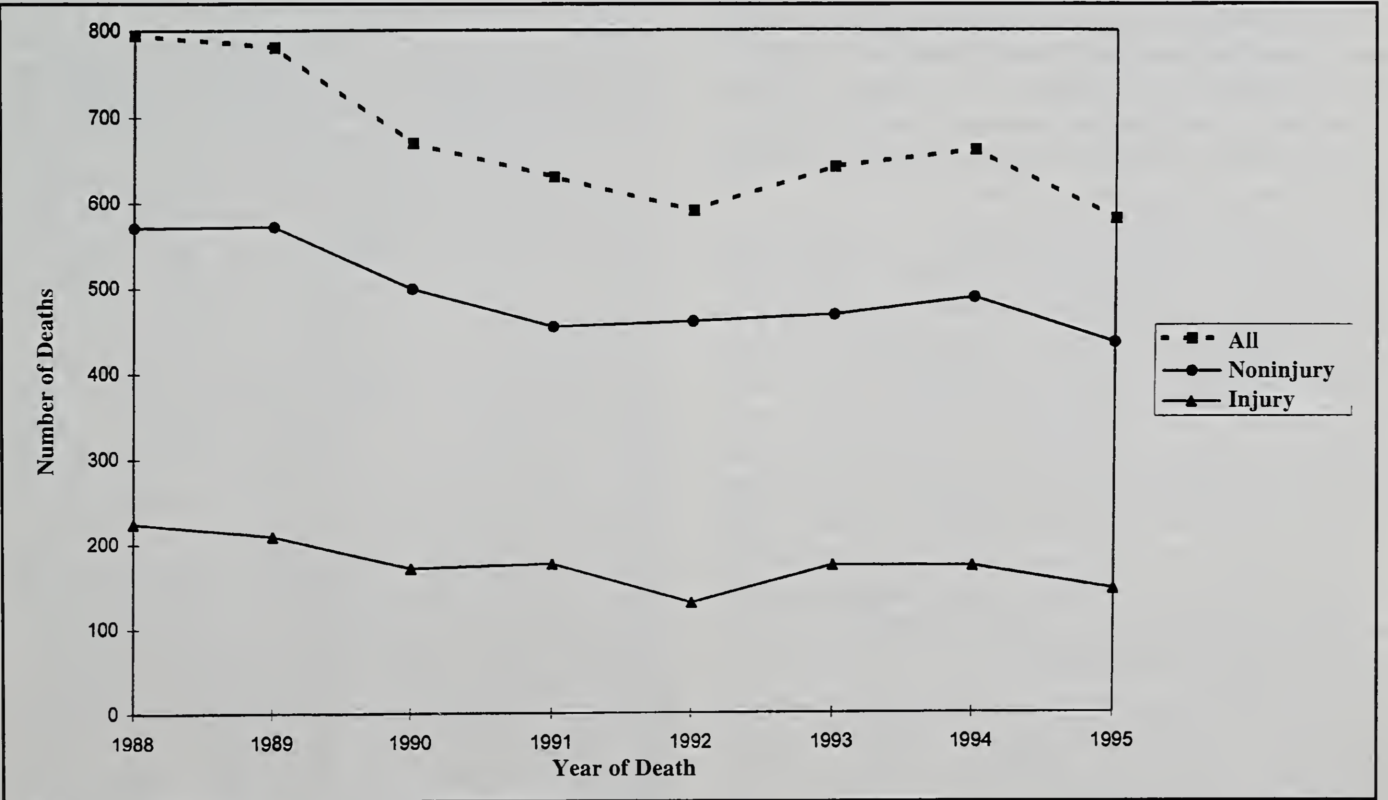

Figure 4.—Fatality trends, 0 to 19 years, Connecticut, 1988–95

The risk of injury by place of residence: Analysis by victim's place of residence shows injury death rates (34 per 100,000, ± 8.6, CI=95%) and injury hospitalization rates (763.7, ± 40.9, CI=95%) to be significantly higher in towns with greater than 100,000 population compared to the other town size groupings (Table 2).

As town size decreases, there is a decrease in child and adolescent homicide (16.4/100,000 for towns >100,000 population; 2.8 for towns 50–100,000; 1.9 for towns 25–50,000 and 0.9 for towns <25,000) and an increase in motor vehicle occupant fatalities (3.4/100,000 for towns >100,000 population; 3.6 for towns 50-100,000; 3.9 for towns 25–50,000 and 6.2/100,000 for towns <25,000). In addition, suicides are relatively less common in cities than in the three smaller town groupings, although suicide attempts resulting in hospitalization are more common in urban areas.

TIME TRENDS: The time trends reported here reflect the date of death, not the date of injury occurrence, and must be interpreted accordingly. Over the eight-year time period injury deaths decreased 35% compared to a similar decline of 24% in noninjury deaths (Fig. 4). The decline in injury deaths is attributable to a 42% decrease in unintentional injuries compared to 17% decline in intentional injuries. For example, deaths from motor vehicle occupant injury decreased steadily from 61 deaths per year in 1988 to 31 deaths per year in 1995. The frequency of homicide and suicide remained the same, approximately 40 and 20 deaths per year, respectively.

Because the rate of E coding increased significantly during the five-year study period from 66% in 1990 to more than 90% in 1994, time trends for nonfatal injury are unreliable and will not be reported. However, analysis shows no difference in the relative frequency of coding specific causes from 1990 to 1994.

THE COST OF INJURIES: One measure of premature mortality is years of potential life lost (YPLL). Each year in Connecticut, an average of 175 deaths are attributable to injury, resulting in 9,928 YPLL. The financial burden of injuries can be appreciated by measuring the use of medical resources. The total charges for 21,148 nonfatal injury inpatient discharges from 1990-94 utilized 94,365 hospital days and approached $155 million dollars. The median cost for a nonfatal injury hospitalization was $3,936. Similar data for the 219 injury patients who died during their hospitalization show 1,206 total hospital days, and median and total five-year charges of $13,133 and $5.6 million dollars, respectively.

Medicaid was listed as the primary expected payment source for 29% of acute-care injury discharges. Commercial insurance (34%), HMO (13%), and Blue Cross (13%) were other payment sources.

Discussion

The success of public health in decreasing infectious disease has far outpaced its success in preventing and treating injuries. In 1910, the major causes of death included tuberculosis and gastrointestinal diseases such as diarrhea. Over the next 80 years, death rates from tuberculosis and gastrointestinal disorders dropped by 99%, while the injury death rate declined by less than a third. Public health strategies such as sanitation, immunization, and treatment of infected persons has dramatically reduced illnesses and deaths from many causes, leaving injury as the leading cause of death for children and young adults.[2] Between the ages of one to 44 years, injury deaths outnumber deaths from all other causes combined.[2–4] Thus injuries are responsible for the greatest loss in years of potential life. If the potential productivity of so many lives could be regained, the economic benefit to Connecticut and the U.S. would be staggering.

Injuries have long been recognized as medical problems, but their public health significance has not been well recognized. Ambulance teams, emergency room staff, and trauma surgeons spend most of their time treating people with injuries. Rehabilitation specialists are well aware that caring for injured patients is one of their most difficult treatment challenges, but despite their major significance to the public health, injuries have only recently been considered public health problems. Few concerted efforts have been integrated within the larger public health context, although highway safety and fire safety programs have existed for some time.

The reason for the lack of effort to prevent injuries has been that most people do not recognize that injuries are preventable. Injuries are considered to be "accidents," and the term, "accidents" implies that these events are neither predictable nor preventable. This misunderstanding is not just a problem for the public, but for professionals as well. Research has shown clearly, however, that injuries are every bit as predictable and preventable as illnesses such as measles, coronary artery disease, and lung cancer.

One example of the predictability and preventability of injuries that has been studied in some detail is the problem of motor vehicle injury, which, in our data, is a leading cause of death and disability for Connecticut teens. For many years, motor-vehicle related injuries and deaths were the sole purview of traffic engineers and scientists. Injuries were regarded as accidents, largely random and unavoidable, with blame assigned to driver error. In the 1960s, Haddon constructed a phase-factor matrix for understanding the etiology and prevention of motor vehicle injury. Building on the epidemiological triangle of host, agent, and environment, Haddon et al developed a framework for motor vehicle collision causation that included human, vehicle, and environmental factors and interactions in time.[7] This prevention framework freed injury prevention scientists and practitioners from limiting their focus to blaming the victim ("tThe accident was caused by a bad driver") and providing acute medical care for the injured ("scoop and run").

What emerged were numerous strategies that proved to be effective in reducing motor vehicle injuries. These included reduction of drinking and driving; laws mandating the use of child car seats and graduated licensure for teenage drivers; passive restraint systems, including seat belts and air bags; and the automotive industry's design and manufacture of antilock brakes, energy absorbing steering assemblies, improved door locks, rounded front ends, tapered dashboards, and reinforced doors and tops. Improvements in roadway design, particularly on the interstate system, also have been credited with saving lives.[2] These improvements include larger and easier to read traffic signs, better illumination, guardrail upgrades, obstacle removal, and crash cushions. Smart vehicle technology, such as sensor alarms to detect vehicles in front and back, promise future reductions in traffic injury and death.[8] Most of these interventions, which have saved many lives and will continue to do so, would not have been possible if it were not for the conceptual development of the scientific priniciples of injury control.

Our data indicate that Connecticut death rates for all injuries are lower than national rates (CT = 20.8 *vs* U.S.=29.4 per 100,000 persons) and several selected causes including motor vehicle occupants (CT=4.6 *vs* US=7.1), homicide (CT=4.8 *vs* US=7.1), and suicide (CT=4.7 *vs* U.S.=6.4).[9] In addition, our data show that childhood mortality and morbidity vary by developmental level and age. Primary prevention programs which match the pattern of childhood injuries must be implemented if the toll of injuries to this otherwise healthy population is to be reduced. Young children often do not recognize situations that place them at risk for injury. Parents and other caretakers sometimes are not aware that children may misjudge a dangerous situation.[10] Education to increase public awareness of the injury prevention methods can help to reduce this major child health risk. Adults can ensure that children under 10 are protected from safety hazards in the home (especially poisons and guns), taught bicycle safety and helmet use, provided controlled access to water recreation, and restrained in motor vehicles. Research has found that lap/shoulder belts, when used correctly, reduce the risk of fatal injury to seat passenger car occupants by 45%.[11] If child safety seats were used correctly (more than half are not), the risk of death and injury would be reduced by 70%.[12] Bicycle helmets reduce the risk of head injury by as much as 85%.[13] The chances of dying in a residential fire are cut in half when a working smoke detector is present.[14] Installation of four-sided pool fencing equipped with self-closing and self-latching gates would prevent 50% to 90% of childhood residential swimming pool drownings and near drownings.[15] Every dollar spent on poison control centers saves $7.75 in medical costs.[12]

The child older than 10 needs clear information about the consequences of risk-taking behavior and close adult supervision to limit such behavior. Excessively careless or risk-taking behaviors among youths should provide a clue to the need for increased support and guidance to prevent self-destructive behavior. Adolescence is a time of rapid physical and psychosocial development often characterized by risk-taking behaviors. At the same time, teens expect and need to have increased freedom. While gaining independence is essential to reaching maturity, adult supervision continues to be necessary to the growing young person. Young drivers need a period of supervised driving experience after driver education and before receiving their driver's license.[16] Regular use of seat belts, helmets, and other protective measures require parent/guardian involvement and enforcement. Drinking while driving may be diminished by organizing drug and alcohol free events, designated driver programs, and by tailoring educational information to the adolescent. Raising the drinking age and enforcing drinking and driving laws have been shown to reduce the death rate among young people.[17]

An important finding of our study was that firearms play an important role in homicides, suicides, and unintentional injury. Over 75% of the homicides, and 55% of the suicides involved firearms. Handguns are involved in 89% of homicides and 59% of suicides among Connecticut youth.[18] Strict enforcement of existing firearm laws, prohibiting the purchase or possession of handguns, and firearm modifications are all strategies which should be pursued to reduce the potential for firearm injuries.[19]

For every child that dies from an injury an estimated 24 are hospitalized. The injury hospitalization rate observed among Connecticut residents zero to 19 years (502 per100,000) is approximately 7% higher than the Massachusetts hospitalization rate (468 per 100,000).[20] Our results are also consistent with other studies that demonstrate that the leading causes of nonfatal and fatal injury are clearly different.[21–23] For example, our data indicate that falls are the leading cause of hospitalization, whereas motor vehicle occupant injury is the leading cause of injury death.

The costs presented for length of stay and hospitalization are but a portion of the price paid for these injuries. This estimate does not include future earnings and quality of life (indirect costs). To calculate cost per injury estimates, we applied figures by the Children's Safety Network Economics and Insurance Resource Center.[12] The costs per injured child are $12,700 and include $650 dollars in medical costs, $1,000 in future earnings, and $11,000 in quality of life. The costs per injured adolescent are $28,200 and include $1,400 dollars in medical costs, $5,900 in future earnings, and $20,900 in quality of life. Using these estimates (in 1997 dollars) Connecticut's annual costs for injury hospitalizations was $79.1 million.

National initiatives for injury prevention and control surged in 1985 when a landmark research effort was published, entitled *Injury in America: A Continuing Public Health Problem.*[4] This collaboration of the National Academy of Sciences' National Research Council, the Institute of Medicine, and the Committee on Trauma Research called for research in epidemiology, prevention, biomechanics, treatment, and rehabilitation. It also recommended the establishment of a center for injury control to be located in the Centers for Disease Control (CDC) of the U.S. Department of Health and Human Services.

Today, the National Center for Injury Prevention funds research grants, Injury Prevention Research Centers at universities, and injury control programs within state health departments. Other federal agencies that work toward injury prevention and control include the U.S. Consumer Product Safety Commission, which is responsible for monitoring the safety of products and regulating the availability of hazardous materials, and the Occupational Safety and Health Administration, which oversees workplace safety. No less important than these professional organizations are lay organizations such as Mothers Against Drunk Driving (MADD), Advocates for Highway and Auto Safety, the National Head Injury Foundation, and the National Safe Kids Campaign. These organizations have amassed significant grassroots support for injury prevention control programs and legislation, and have provided supportive services and education for those affected by injury.

Connecticut's initiatives for childhood injury prevention and control have paralleled national initiatives. The Connecticut Childhood Injury Prevention Center (CCIPC) provides leadership in research and in the translation of that research into prevention programs and policy. The CCIPC trains local officials in injury control and provides education and training for medical students at the University of Connecticut School of Medicine, residents in the pediatric residency program, and graduate students in public health and social work. The CCIPC is also the home for Connecticut Safe Kids, the state affiliate of the National Safe Kids Campaign.

At the level of state government, injury prevention activities have been sponsored by a number of agencies including the Departments of Public Health, Transportation, and Consumer Protection as well as the Connecticut Poison Control Center. Local health, police, and fire departments often collaborate with Connecticut Safe Kids and carry out specific projects. Citizen groups are also important contributors to the injury control effort in Connecticut. The Connecticut Traumatic Brain Injury Foundation is a leader among private groups of layman and professionals for its work to promote awareness, prevention, treatment, and rehabilitation for brain injured persons and their families. Organizations such as MADD, and the Connecticut Coalition Against Gun Violence have been particularly effective in promoting public awareness and legislative actions to reduce injury. Other groups such as the New Haven Regional Injury Prevention Program sponsor prevention activities addressing both unintentional injury and violence in New Haven county.

In summary, injury prevention and control is important for Connecticut to reduce the toll of death, disability, and financial expense that results from injuries. Although initiatives for injury prevention and control have been slow to develop, major federal programs are redefining the injury problem and providing resources for state and regional efforts. The burden of childhood injury morbidity and mortality is large in Connecticut, but we have already begun to apply scientific and technical resources to the problem. These resources have come from our academic medical centers, from state government, from local health departments and professional groups, and citizen's groups. The findings of this study build upon our progress and identify priorities for continuing action.

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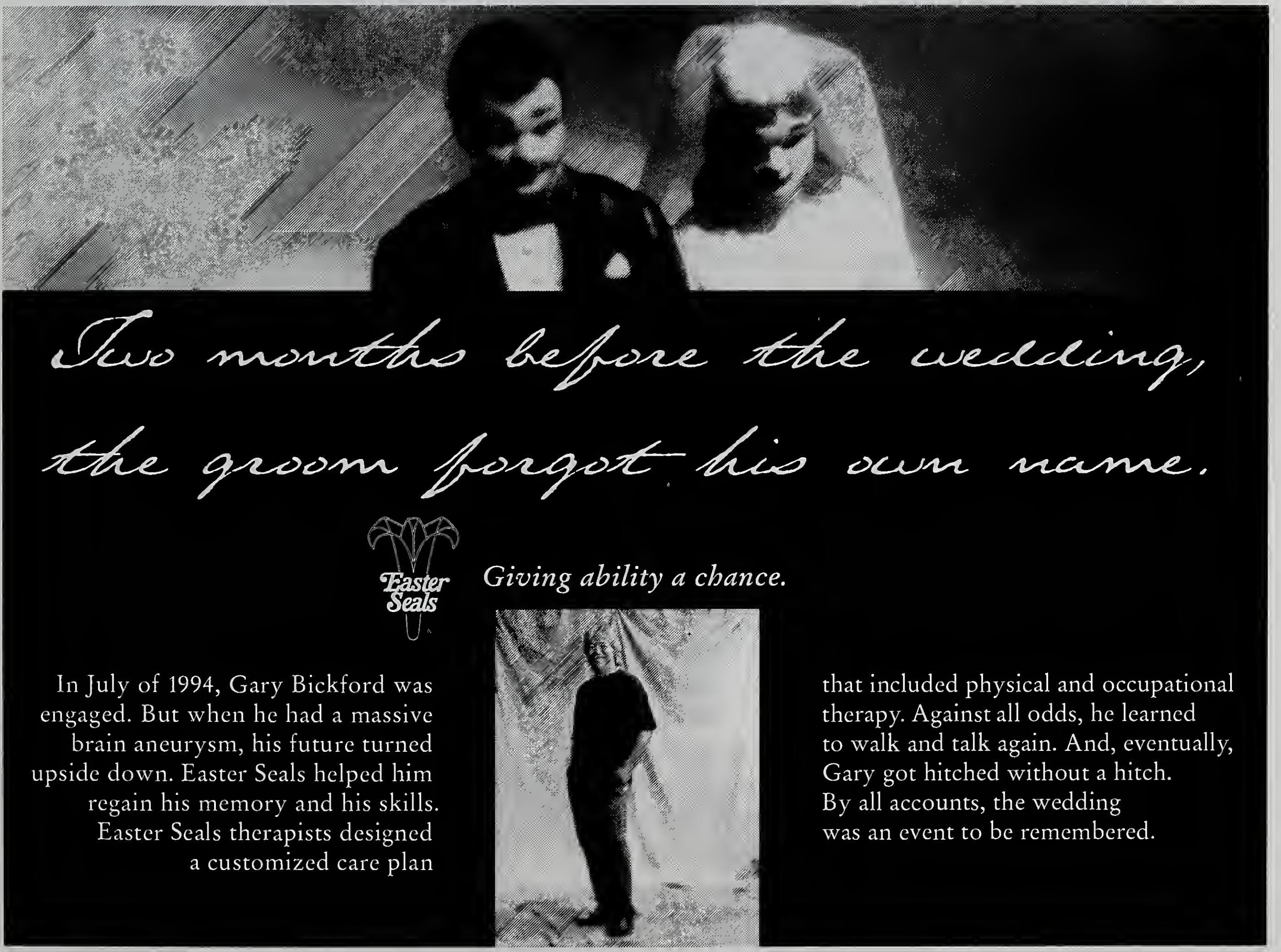

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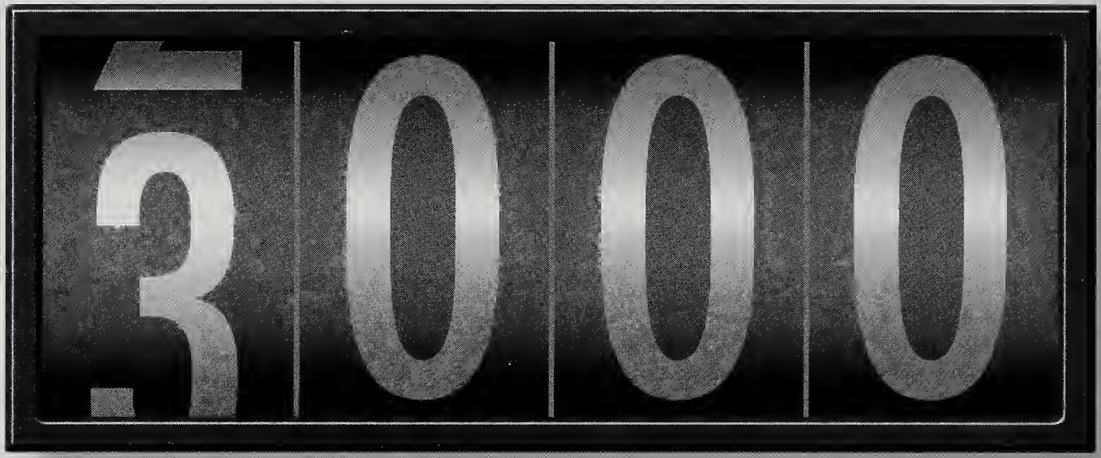

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Workplace Violence: Occupational Safety and Health Administration Guidelines for Workers in Health Care and Social Services

MARCIA TRAPÉ, M.D.

ABSTRACT—Workplace violence has become a problem in modern American society. Health-care workers are particularly vulnerable because of the nature of their jobs dealing with clients, many of whom are emotionally disturbed. A brief review of the Occupational and Safety Health Administration (OSHA) "Guidelines for Preventing Workplace Violence Among Health Care and Social Workers" that was published in 1996 is presented. Some sensible ways to implement the OSHA guidelines are also discussed.

Introduction

VIOLENCE in the workplace may seem like a trivial and mostly preventable problem unless one is directly affected by it. As an internist working for a state psychiatric hospital, I never gave it much thought until one day a patient almost knocked me out. I was always careful, as I knew many of my patients suffered from dementia and other mental illnesses with serious impulse-control problems. At the time of the patients' annual physical examinations, I would have the nursing staff help me, and even with the most aggressive psychotic patients, I was generally able to perform their examinations without problems.

On the day that I was struck, it was a quiet afternoon in the geriatric unit. Most of the patients were asleep on their beds or in their geriatric chairs. Mr. S. was wandering down the hall in his slow parkinsonian gait. I stayed on my side of the corridor as I went by him. When I got to the nursing station, I saw the nursing staff doing their chart notes quietly, and I could hear the noise of two old men slapping each other while sitting in their geriatric chairs. I mentioned to the nurse that I was going to separate the chairs, and, as I turned around, Mr. S. hit me on the right side of my jaw with his locked right elbow. I screamed and moved away from him. The nurses came to my rescue. My lip began to swell and was bleeding slightly, hardly anything I would not survive. However, I was upset and felt vulnerable for a long time afterward.

Throughout my career at the psychiatric hospital, I attended many physicians, nurses, and other staff members who had been assaulted by patients. Many worked without any injuries for decades until that first assault. I also attended several employees who had violent acts perpetrated against them, usually by spouses or companions, while on their way to the workplace, during lunch, or at breaks. Home violence frequently spills over into the workplace.

I was happy to learn that the problem of violence at the workplace was to be given attention when the Occupational Safety and Health Administration (OSHA) published the "Guidelines for Preventing Workplace Violence Among Health Care and Social Service Workers" in March 1996. My objectives here are to review the importance of the OSHA guidelines with regard to violence in society, and to review the principle aspects of these guidelines for implementation by employers.

Background

American society is considered by many as one of the most violent in the world today. The American homicide rate is 10 times higher than that of England and 25 times higher than that of Spain.[1] Of 6,271 fatal work-related injuries in 1993 in the United States, 17% were homi-

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MARCIA TRAPÉ, M.D., F.A.C.P., medical director, Employee Health Service, Division of Occupational and Environmental Medicine, assistant professor of Clinical Medicine, University of Connecticut School of Medicine.

cides.[2] In five states, including Connecticut, homicide was identified as the leading cause of workplace death during the past decade.[3]

Furthermore, the National Traumatic Occupational Fatalities (NTOF) office, which maintains a database on deaths caused by injury at work in individuals 16 years of age and older, has concluded that homicide is the leading cause of work-related death among female workers (data analyzed from 1980 through 1992).[4] In California, occupational homicide accounted for 48% of the fatalities among all women's work-related injury deaths during 1993.[5]

There is also a consensus that health-care workers are especially vulnerable to violence because of the type of work they perform. Goodman reported that, from 1980 to 1990, 522 health-care workers died from work-related injuries; of those deaths 20.3% were homicides and 73.6% of those homicides were caused by firearms.[6] The Bureau of Labor Statistics reported that health-care workers were frequently victims of nonfatal violence at the workplace, due mainly to encounters between nurses and nurses aides with patients, many of them with mental illness.[7] The average time lost away from work for these workers to recuperate was three to five days, according to 1993 data.[8] However, patients with chronic mental health disorders are not necessarily more violent than the nonmentally ill when they are properly medicated in the ambulatory setting.[9-10]

The Occupational Safety and Health Act of 1970, under the "General Duty Clause" requires employers to provide workers with a place of employment free from recognized hazards likely to cause death or serious physical harm.[11]

Risk Factors for Workplace Violence

Several risk factors for violence in the workplace were identified by the National Traumatic Occupational Fatalities Surveillance system:[12]

- contact with the public
- exchange of money or jewelry
- working alone or in small numbers
- late night or early morning hours
- working in high crime areas
- guarding valuables or property
- working in community settings
- working with individuals known to have a propensity for violence, with a history of assaultive behavior or exhibiting belligerent, intimidating, or threatening behaviors.

Strategies for Preventing Workplace Violence

What has been done to prevent violence in the workplace? Several initiatives have been developed and implemented in an attempt to control this problem. Washington State and Florida have enacted laws requiring owners of retail stores to put in place crime prevention and training programs.[13-14] North Carolina and California recognized that state government employees who provide services to the public are at increased risk of violence in the workplace.[15-16] There are some initiatives in place across the U.S. to protect workers, including surveillance programs and safety training for workers. A recent study of one of these programs in Washington State showed that, although awareness among employers remain low, the regulatory efforts have resulted in increasing numbers of preventive programs provided to workers.[17]

California OSHA published "Injury and Illness Prevention Program for Workplace Security," "Guidelines for Workplace Security," and "Guidelines for Safety of the Health Care and Community Service Workers."[18-20] Other states, including New Jersey and Washington, have also published guidelines on prevention of violence for workers.[21-22]

Federal OSHA released "Guidelines for Preventing Workplace Violence Among Health Care and Social Service Workers" in March 1996.[23] These, however, are not mandatory, but have only an advisory role, and are not considered standards or regulations. However, under the "General Duty Clause" of the Occupational Safety and Health Act, employers can be cited if there are recognized hazards of workplace violence and the institution or employers have not done anything to reduce their risk.

Essential Elements of a Successful Program

The fundamentals for effective programs are well delineated by Askari and comprise the following:

1. *Labor and management commitment and involvement to implement a violence prevention policy*.—Workers must be involved if this project is to be successful. One person from senior management should be identified as responsible for the development and implementation of the project. Supervisors also must be involved from the initial stages of planning. A written plan is highly recommended.

2. *Risk assessment.*—A risk assessment must be undertaken, considering the institution, its safety and violence records, and areas where violent acts have occurred. Threats need to be taken seriously in the risk analyses. Surveys may be utilized to obtain data from all employees. A zero tolerance policy for violence is the approach of most private business.

3. *Hazard Prevention and Control.*—a) Engineering controls should be implemented. Special attention should be paid to the building and room design, emphasizing security measures, such as locks, barriers, metal detectors, bullet proof glass, drop safes, alarm systems, panic buttons, and clear visibility inside and outside. Landscaping should be appropriate and not block the view.

b) Administrative and work practice controls should include adequate staffing, adequate training of staff, policy against working alone, escort service for staff or patients leaving the institution at late hours or a buddy system, special procedures to handle and/or report threatening or violent situations, and formal reporting of all threats of violence and assaults.

4. *Incident response and counseling.*—Ensure that there is a team to do an in-depth debriefing. After an incident with violence, give the involved employee access to an Employee Assistance Program counselor for evaluation; extended counseling should be provided if deemed necessary.

5. *Training.*—All employees, including supervisors and managers, should be trained regarding violence prevention. Special groups of employees at higher risk for specific hazards would require special training. Simulations or drills are recommended as effective training models. Periodic revision of the training should be provided, probably annually, or more often as designated by the institution. All newly hired or reassigned employees should receive orientation on violence prevention.

6. *Record keeping.*—Record keeping is essential to evaluate the program by identifying trends, formulate corrective measures, and assess the need for additional training.

All injuries related to violence must be recorded in the OSHA Log of Injury and Illness (OSHA 200) if more than first aid care is involved. However, injuries or incidents not recordable in the OSHA 200 Log, such as verbal attacks or aggressive behavior, should be recorded in a separate database or incident reporting system. Workers with a history of abusive or violent behavior, including criminal activities in the past and drug abuse, should have these elements of their history documented to help staff identify potential risks. Records of training activities should also be kept, including qualifications of instructors and attendance lists.

7. *Evaluation of the program.*—A system for periodic evaluation and reporting of the prevention program should be set up. Surveys should be used before and after changes are made in the workplace. Reports on trends and rates should be reviewed periodically by safety committees, labor management committees, and other institutional forums. These reports should be made available to workers and management.

Summary

Living in a violent society puts us at risk for violent acts. Workplace violence may be dealt with effectively through a proactive preventive approach. The OSHA guidelines provide an impetus for both employers and employees to discuss ways to implement programs that will prevent workplace violence.

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Teaching Senior Medical Students in an Office Setting: The Apprentice System Revisited: A Cardiologist's Perspective

ARTHUR O. PHINNEY, JR., M.D. AND W. DAVID HAGER, M.D.

ABSTRACT—The recent changes in medical school curricula, brought about by insurance companies, government agencies, and market forces have shifted the focus of patient care from hospital bedside to office or clinic. Classic approaches to the teaching of medical students in the subspecialties have become confused and inadequate. Students' confidence in their own clinical expertise has been hampered by lack of teaching and guidance, and these functions cannot be filled by higher technology. We have completed a successful four year project for fourth year students utilizing a busy practice of cardiology/ internal medicine in monthly electives. Among the objectives were to share the real life practice of medicine primarily in an office setting thereby decentralizing patient care and teaching outside of the medical school; to help students gain experience and confidence in the *clinical* skills of diagnosis and to help them choose "high tech" procedures that are appropriate, and have acceptable cost/benefit ratios; and to recruit an enlightened teaching faculty from practicing physicians who will become medical student advocates, facilitators, and role models, especially for the difficult years of managed care ahead.

The elective met with enthusiastic support from all students, whose follow-up letters from residencies confirmed the practical value of the course in clinical skills as well as in choice of appropriate higher technology. Although poorly compensated at present, a few plausibel suggestions are offered. If structured and coodinated efficiently this practical experience for students can be a real incentive for continued education, inspiration, and pleasure for the faculty monitor, without compromising his or time or income.

Introduction

IT was the Flexner Report[1] in 1910 which signalled the decline of the apprentice system in medical education and training. A new set of standards was advanced, standards for medical admissions, degree of scientific training, and quality of clinical teaching, and the new era, under which we all were educated—the "biological–anatomical model"—was developed. Before this, other than a few lectures viewed from afar, usually from an amphitheater, medical student teaching was largely apprenticed to the practioner. This practical experience was highly variable, incomplete, and dependent, of course, upon the caliber of the physician or mentor. It was only the clinical clerkship which kept alive the art of mentoring, or the apprenticeship.[2,3]

The radical changes today, brought about by market forces, insurance companies, and government agencies are forcing many restrictions of time and money on both the administrative and professional faculties of medicine. With fewer hospital beds and shorter in-hospital stays there has been a dismanteling of much of the traditional and proven undergraduate educational curricula. The spectrum of in-hospital diseases has narrowed, with over 75% of bed occupancy filled with seriously ill or terminal patients, mainly AIDS, cancer chemotherapy, or intensive care patients These patients are less suitable for teaching

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the basics of history taking, physical examination, and clinical evaluation. Managed care has not seen fit to accept the responsibility for undergraduate education or clinical training, in a profession where intensive clinical instruction and guidance are crucial. Cost containment and commercial interests have become mandatory and exclusive.[4-6] Despite the clinical clerkship and a 600% increase in the number of clinical, full-time medical school faculty, the availability of student mentors has decreased drastically,[7] and clinical skills are disappearing.[8]

In addition, the high cost of rapidly advancing technology and the attempted cost containment by managed care have produced a strange paradox. Highly technical procedures (high tech) have overwhelmed the discipline. Clinical judgment, and indeed much of the pleasure of bedside diagnosis and clinical management, taught to us by such master-teachers as Herman Blumgart, Paul White, Soma Weiss, Paul Wood, and many others in the tradition of William Osler, is being lost. Dependence on these procedures has led to student insecurity in clinical assessment.[9] Unskilled history taking and physical examination lead to inappropriate ordering of these diagnostic procedures. Frequently, clinical reasoning and accountability are lacking, thus promoting even more high tech dependency, and a further reduction in basic clinical skills.

The challenge for undergraduate medical education is to design a high quality outpatient, and community based teaching program using practicing physicians, and clinic or office patients; to create a university—community hospital partnership or *network*, allowing both to maintain their traditional activities in research, teaching, and patient care.[10] Over the past five years we have developed a successful elective for fourth year students which has many similarities to the old apprenticeship system, guided by a syllabus or core curriculum, and by knowledge of changing medical school goals, in a newly developing managed-care setting,[11] using problem-based, evidence-based, and patient-centered learning.[12-14]

Objectives

1. "To share the real life practice of medicine in a daily office setting, at the same time decentralizing patient care and teaching outside of the medical school, and to acquaint students with various styles of efficient patient management,[9,11-15] and a variety of cardiovascular syndromes and problems.

2. To learn that responsibility for patient welfare is the legacy of physician education and the reason why most of us chose medicine—so easily overlooked in the wonder of newer technology,[15] and to gain satisfaction from caring for patients in addition to helping to cure them.

3. To offer a practical foundation in basic "low tech," ie, competent history and physical examination; to allow opportunities for students to be involved in noninvasive office procedures; to be aware of the shortcomings of "the clinical examination," and yet come up with a working diagnosis before ordering sophistocated invasive procedures.[16]

4. To help students choose appropriate high technology diagnostic procedures high tech, learn to be critical in accepting the results, and educate them in the cost/benefit ratio of these procedures.[17-19]

5. To recruit a teaching faculty from practicing physicians who have a passion for teaching, and who recognize that their involvement in this kind of commitment is the key to their continued education, and to greater satisfaction in their practices.[17-19]

Requirements and Methods

The elective was open to seniors who had completed third-year medicine, and was one of over 100 electives offered by the University of Connecticut School of Medicine. It consisted of a month of cardiology/internal medicine for two or three students at a time, in my private office, adjacent to a large teaching community hospital, the Hartford Hospital. The office included noninvasive cardiac investigative equipment for EKG, exercise testing, Holter monitoring, and echocardiography, and a supporting staff of medical technicians and nurses. Hospital rounds were facilitated by a "network" of colleagues based in the hospital, who enjoyed teaching senior students in cooperation with this elective course. The course was popular; oversubscribed a year in advance, and consisted of six separate activities: 1) 8 A.M. daily conferences, lasting an hour, to cover the syllabus; 2) participation in daily office practice; 3) hospital rounds for inpatients; 4) attendance at various diagnostic procedures (especially on assigned patients); 5) attendance at other scheduled hospital conferences; and 6) a journal club presentation of two selected or self-chosen reading assignments relative to one of the current "controversies in cardiology."

Table 1 outlines the syllabus covered in the 8 A.M. conferences:

FIRST WEEK: Basics of clinical, office cardiology, using the differential diagnosis of chest pain to demonstrate the intricacies of an efficient history, electrocardiography, echocardiography, Holter, and exercise monitoring.

SECOND WEEK: Further diagnostic procedures, medical management, indications for invasive cardiology, and radionuclide cardiology.

THIRD WEEK: Appreciation of sophisticated 'high tech,' for a small percentage of diagnostic problems, and inclusion of students in office decisions and future planning. Students become "externs."

FOURTH WEEK: Use and misuse of invasive procedures, and understanding the process of patient education and management. The presentation of student assignments included the two research reading assignments covering such controversial subjects as collateral coronary circulation, balloon angioplasty *vs* bypass surgery, risk patterns for arrhythmias and sudden death and proarrhythmic drugs, the treatment of hypertension and congestive failure, diabetic cardiomyopathy, and many others.

The office practice.—More emphasis was placed on seeing a volume and variety of clinical syndromes rather than on meticulous and time-consuming history taking Coping with the pace of a busy office schedule emphasized flexibility, reliable "interim" histories, rapid identification of physical signs, and succinct chart notes. Students had first-hand experience of patient education, and learned something about effective, up-to-date office management dealing with managed care and billing procedures. They learned to work with office nurses and medical technicians.

Results

Teaching clinical medicine has become a complex undertaking. Many changes have occurred over the past 15 years, which might best be summarized as follows:

1. Predominately office or clinic setting
2. Almost entirely problem-based
3. Patient oriented, rather than physician centered
4. The biological-anatomical model is still basic, but guided by "clinical pathways" and algorhythms, which, unfortunately, tend to drive physicians away from their patients.
5. High-technology driven, often without the judgment of a clinical setting.
6. Curtailed by managed care, with cost containment and "cost shifting" in a profession grossly unsuitable to be profit-driven.
7. The trend towards family medicine and away from specialty consultations
8. Wider spread of health-care delivery, nursing responsibility, and emphasis on preventive medicine, with widespread use of VNA, physician assistants, home health care, physiotherapy and chiropractic, acupuncture, vitamin fads, and alternative medicine
9. Increased complexity of cases, and sophistication of patients, requiring "intensivists" in ICUs and emergency wards.
10. The doctor is no longer "in charge."

Comments and Discussion

When structured, monitored, and coodinated efficiently, this course for fourth-year students proved to be mutually beneficial to both students and mentor, allowed more responsibility for the students as they became virtual "externs" in their third week, and exposed them to a wide variety of cardiac and internal medicine problems. I found that the excitement and privilege of sharing my care and management of patients was most satisfying. Full-time medical school faculty now welcome the teaching efforts of selected practicing physicians, and the potential and interest are high and should be fully utilized. The rewards have been in the inspiration and enjoyment of teaching, and in becoming a dynamic part of the new medical school curriculum. This curriculum includes involvement of the

Table 1.—Weekly Schedule of Activities: Fourth Year Students

First Week:	1.	The stratagem of effective history taking and the differential diagnosis of angina, palpitations, dyspnea, and syncope, all pertinent to the cardiovascular system.
	2.	Office examination of the cardiovascular system including heart size and rhythm, heart tones and murmurs, and common musculoskeletal considerations.
	3.	Chest roenntgenography: basics of interpretation and clinical correlations.
	4.	ECG: Arrhythmias, myocardial infarction patterns, LVH, and bundle branch block.
	5.	Basics of echocardiography: indications and limitations
Second Week:	1.	Medical management of angina and myocardial infarction.
	2.	Coronary angiography, angioplasty, atherectomy, and stents.
	3.	Swan-Ganz catheter indications and interpretations
	4.	Treadmill exercise tests with and without radionuclides
	5.	Indicator dilution techniques and left heart catheterization
	6.	Holter monitors and common arrhythmias
Third Week:		Indications and assessment of multiple gated acquisition scan (MUCA), computerized axial tomography (CAT scan), transesophageal echocardiography (TEE), magnetic resonance imaging (MRI), and cardiac rehabilitation in long-term mamagement of cardiac patients.
Fourth Week:	1.	High technology procedures: Use and misuse of invasive and noninvasive techniques
	2.	Bedside and office teaching sessions, admissions, and follow-ups
	3.	Student presentations of their reading and research assignments

patient in decisions, and in ethical considerations involving high tech procedures. It also includes emphasis on two major omissions from the biological/anatomical model : our rapidly increasing knowledge of the behavioral sciences and their influence on our understanding of disease processes, and a major emphasis on preventive medicine.[20-22]

However, decentralization of patient care may cause confusion of schedules and inefficient student monitoring. Basic patient trust and loyalty have become threatened, as managed care and high technology proliferate.[18] There is less time to teach or advise students. Students need a facilitator, an advocate, and a role model.[21-22] These functions cannot be filled by advancing higher technology. In fact, the unmonitored ordering of high tech procedures is usually based on both inexperience and insecurity. This insecurity is often the result of early medical school exposure to high tech procedures themselves, without asssessing the possibilities that the test may not change the diagnosis, the management, or the course of the disease. This preceptorship, or "mentorship," was designed to assess the strangths and limitations of basic history and physical findings as well as those of high tech procedures.

Office dynamics.—One of the most interesting experiences was to recognise the complexity of the office patient/student/physician relationship.[23-27] "You have personally examined my husband yourself, haven't you, doctor?," inquired the wife of the patient being examined by the students, on my return from the examining room. "I felt during my last visit, which included students, that your attention was directed too much to the students," confided one long-time patient on his follow-up visit. However, all patients seemed pleased to have another professional consulted, even a student.[19] Patient/student repartee was active and friendly. Students introduced themselves by their first names. They were quick to see that an efficient office staff and a relaxed office setting were preferable to a crisis environment for promoting patient understanding and compliance, and especially for the elderly, the chronically ill, and the "difficult" patient.

Evaluations.—Student evaluations of the elective were universally favorable and enthusiastic, as judged by daily performance, by required narrative evaluations, and by subsequent letters from them in their residencies. In a one-to-five assessment questionnaire all students rated the elective as five, or excellent. Assessment of *student* improvement in clinical skills is difficult to quantify, especially in a busy office setting. However, the daily 8 A.M. seminars provided an on-going evaluation of student knowledge of syllabus content, as well as an appraisal of clinical judgment and performance. A final report and evaluation on each student was filled out and sent to the dean's office, based on my own observations and the student's responses in the daily seminars.

Conclusions

1. Teaching at a fourth-year medical student level is a very rewarding experience. There should be more opportunities for the practicing physician, who can be an advocate, a facilitator for students, and who supplies a much needed role model. With the recent trend towards medical school involvement in the community, and with changing medical school-practicing physician laisons, the challenge to the medical school is in finding competent clinical teachers.
2. With a minimum of time needed, the physician can craft an efficient daily program of academically focused, practical medicine, and become a dynamic part of the new medical school curriculum.
3. Such an elective in a medical specialty should be managed by either a specialist with broad-based training in internal medicine, or by a generalist with special teaching interests. The elective must be well organized, and guided by a carefully considered syllabus.
4. Further possibilities for compensation for a part-time clinical faculty should be explored.[28] This compensation might cover malpractice, liability and health insurance; licensure and professional dues ; capitation equivalents in case of further trends towards that phase of reembursement; and a nominal academic appointment on the medical school faculty. Further support from both medical school and managed care is needed.
5. Accountability of teaching and community hospitals for Medicare HCFA and State reembursement for teaching should be examined more closely, as possible future part time remuneration.
6. This was a pilot project that was highly successful, and could easily be replicated, but needs full integration into and trust by the medical school. There is a large pool of clinical talent from academically inclined, practicing physicians which should no longer be wasted, and could add a great deal to undergraduate medical education and training.

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Mortality Among Children with Sickle Cell Disease Identified by Newborn Screening During 1990-1994—California, Illinois, and New York

SICKLE cell disease (SCD) is an autosomal recessive disorder characterized by production of abnormal (sickle) hemoglobin, resulting in anemia, susceptibility to pneumococcal and other infections, pain, stroke, and multiple organ dysfunctions. The most common types include hemoglobin SS (homozygous) disease, sickle cell-hemoglobin C disease, and the sickle beta-thalassemia syndromes.[1] A randomized controlled trial published in 1986 indicated that daily oral penicillin prophylaxis reduced the incidence of serious infection in young children with SCD and led to widespread adoption of newborn screening programs for SCD.[2] To study the effectiveness and utilization of prevention programs among large populations of infants with SCD, several newborn screening programs in the United States are now attempting to determine rates of complications and actual use of early medical interventions (eg, penicillin prophylaxis and pneumococcal vaccination). This report focuses on recent mortality in California, Illinois, and New York. In California and Illinois, mortality from all causes among black children born during 1990–1994 with SCD was slightly less than overall mortality for all black children born in the same time period.

All newborns in California, Illinois, and New York are screened for hemoglobinopathies. Health departments implemented screening programs in New York in 1975, Illinois in 1989, and California in 1990. For this investigation, SCD was defined as any clinically significant sickle hemoglobinopathy in an infant born during 1990–1994. In California and Illinois, identifying variables from SCD databases were matched with computerized records of state-specific death certificates for 1990–1995. In New York, all SCD-related deaths among children aged <3 years listed in state vital records for 1990–1994 were matched with the state SCD database. Additional follow-up extending through 1997 was available in California and Illinois: local physicians (ie, through surveys) and public health nurses informed the respective state health department about the circumstances of SCD-related deaths; such information was not available in New York. Mortality rates per person-year were calculated assuming complete death ascertainment through December 31, 1994, in New York and through December 31, 1995, in California and Illinois.

During 1990–1994, a total of 2,487 children with presumed or confirmed SCD were identified by the three newborn screening programs. Excluding two deaths of children presumably born in other states, 27 deaths were reported among children with SCD; 20 death certificates provided causes that included SCD or other conditions related to SCD (Table 1). The median age at death for the 20 infants who had SCD-related deaths was 22 months (range: 2–53 months). Mortality rates for each state were similar. In California and Illinois, where mortality for all causes was ascertained, by the end of 1995 the cumulative mortality rate was 1.5 per 100 black children with SCD born during 1990–1994. The equivalent cumulative mortality rate for all black children born during this period in California and Illinois was 2.0 per 100 black newborns, based on approximate age-coded data in national multiple-cause mortality files.[3]

Mortality data was available until the third birthday for the subgroup of 768 children with presumed or confirmed hemoglobin SS disease born during 1990-1991 in New York and during 1990–1992 in California and Illinois. Of these 768 children, 1.0% died as a result of SCD-related causes during the first three years of life (0.35 per 100 person-years, based on 2258 person-years [95% confidence interval=0.15-0.70 per 100 person-years]). The rate of compliance with penicillin prophylaxis was unknown; an investigation of risk factors is being conducted to

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Table 1.—Sickle cell disease (SCD)*-related deaths among children born during 1990–1994, by state and year of birth, age at death, and cause of death—California and Illinois (1990–1997) and New York (1990–1994).

State/ Year of birth	Age at death (mos)	Other cause(s) of death§
California		
1990	48	—
1992	8	—
1993	31	Congestive heart failure, pulmonary edema/effusion
1994	2	—
1994	12	High fever and sepsis
1994	13	—
Illinois		
1990	15	Myocarditis
1990	17	Pneumococcal meningitis
1990	45	Sepsis
1991	7	Septic shock, pneumococcal meningitis
1991	23	Pneumococcal sepsis
1992	53	Sepsis
1994	39	—
New York		
1990	25	—
1990	27	—
1990	29	—
1992	13	—
1992	17	—
1992	21	HIV infection
1992	23	—

*All children had presumed hemoglobin SS (homozygous) disease, except one child with sickle cell-hemoglobin C disease who died at age 53 months.

†The following deaths were excluded: three children aged <1 month whose deaths were attributed to extreme prematurity or birth defects; one child aged 42 days who died because of pneumocystosis; one child with presumed sickle-beta thalassemia who died at 47 days of age because of pneumonia; one child with cerebral palsy and seizures whose death was attributed to aspiration pneumonia; and one child who had a traumatic death.

§In addition to SCD. For 11 children, only SCD was listed as a cause of death.

analyze this and other factors in relation to death and other serious complications. Information about risk factors will be obtained through parental and physician surveys.

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Editorial Note: The findings in this report indicate low mortality rates for children with SCD born during the early 1990s in geographic areas in which infants with the condition are identified soon after birth. Early diagnosis is an important component of comprehensive medical care for affected children.[1,4] In a study of U.S. death certificates for 1968-1992, mortality among black children aged one to four years who had SCD declined significantly.[5] This trend occurred at the same time as the establishment of newborn screening programs, more comprehensive care and parental education, widespread acceptance of penicillin prophylaxis after publication of the randomized trial in 1986, and new vaccinations.

Although the mortality rate for children with hemoglobin SS disease described in this report is lower than comparable rates in earlier studies, comparisons between these mortality rates and those from clinical studies, the Cooperative Study of SCD, and national death certificates must be interpreted cautiously because of differences in study design and ascertainment of deaths.[5-7] One limitation of this investigation is that deaths outside the three states would not have been ascertained. Under-ascertainment of deaths also could have occurred through errors in matching or reporting of vital statistics. This study was population-based, and mortality rates were relatively stable because of the large number (2,487) of young children with SCD.

In Maryland, the mortality rate for black children with SCD was comparable to, or lower than, the mortality rate for all black children during 1985–1994.[8] Underascertainment of SCD among severely ill neonates could account for this finding, but ill children in neonatal intensive-care units usually are screened for SCD. In California, Illinois, New York, and Maryland, comprehensive medical care and public health interventions may have contributed to the observed reduction in premature mortality from all causes.

Newborn screening follow-up studies are useful for evaluating the prevention effectiveness of public health programs, which is an essential component of applying genetic technology to disease prevention.[9] Follow-up studies can determine whether public health programs that are widely implemented have the prevention impact that the randomized trials predicted. Continued evaluation overtime of comparable data for hemoglobinopathies and other newborn conditions can provide epidemiologic evidence of the clinical value of screening programs for these conditions. More detailed analysis of risk factors for adverse outcomes among children who have SCD also will assist public health agencies with targeting prevention programs for specific high-risk groups.

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THE MEDICAL LETTER

Toremifene and Letrozole for Advanced Breast Cancer

THE antiestrogen toremifene *(Fareston*—Schering) and the selective aromatase (estrogen synthetase) inhibitor letrozole *(Femara*— Novartis) have been approved by the FDA for treatment of advanced breast cancer in postmenopausal women.

SOME HORMONES FOR BREAST CANCER

Drug	Usual daily Dosage	Cost*
Tamoxifen—generic (Barr)	20 mg PO qd	$97.26
Nolvadex (Zeneca)		97.88
Toremifene—Fareston (Schering)	60 mg PO qd	97.26
Anastrozole—*Arimidex* (Zeneca)	1 mg PO qd	187.20
Letrozole—*Femara* (Novartis)	2.5 mg PO qd	187.20
Megestrol acetate—generic	40 mg PO qid	80.48
Megace (Bristol-Myers Squibb)		161.95
Aminoglutethimide—Cytadren (Novartis)	250 mg PO qid	135.43

*Cost to the pharmacist for 30 days' treatment based on wholesale price (AWP or HCFA) listings in Drug *Topics Red Book* 1997 and March 1998 *Update.*

HORMONAL TREATMENT FOR ADVANCED BREAST CANCER—Hormones frequently used for treatment of advanced breast cancer include antiestrogens such as tamoxifen, progestins such as megestrol acetate, aromatase inhibitors such as anastrozole (*Medical Letter* 1996; 38:61), or aminoglutethimide, and luteinizing-hormone-releasing hormone (LHRH) agonists such as leuprolide *(Lupron)* or goserelin *(Zoladex).*

TOREMIFENE—Antiestrogens compete with endogenous estrogen for estrogen receptors, inhibiting the growth-stimulating effects of the hormone. A triphenylethylene derivative, toremifene (toré em i feen) is structurally similar to tamoxifen. Like tamoxifen, it has antiestrogenic and, at least in the uterus, weak estrogenic activity.

Pharmacokinetics—Toremifene is almost completely absorbed after oral administration, reaching peak plasma concentrations in about three hours. The drug is extensively metabolized by the liver, predominantly by CYP3A4, and the metabolites are excreted mainly in feces, with a half-life of about five days.

Clinical Trials—Three large randomized trials in previously untreated postmenopausal patients with estrogen-receptor-positive or receptor-status-unknown advanced breast cancer have found toremifene 60 mg/day similar to tamoxifen 20 or 40 mg/day in response rates (about 20%) and median survival (about 30 months); in one study the median time to progression was about three months longer with tamoxifen (Hayes DF, et al, *J Clin Oncol* 1995; 13:2556; Pyrhonen S, et al, *Br J Cancer* 1997; 76:270; Gershanovich M, et al, *Breast Cancer Res Treat* 1997; 45:251). Use of toremifene 200 mg/day in tamoxifen-refractory patients produced only a 5% objective response (Vogel CL, et al, *J Clin Oncol* 1993; 11:345).

Adverse Effects—Hot flashes have been the most common adverse effect of toremifene. Nausea, sweating, and vaginal discharge have also occurred commonly. Dizziness, peripheral edema, vomiting, vaginal bleeding, and hypercalcemia have occurred occasionally. Dry eyes, cataracts, and increased aminotransferase activity have

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been reported. Thromboembolic events have occurred rarely. This pattern of toxicity is similar to that of tamoxifen. Toremifene has not been studied long enough to determine whether it has any carcinogenic effects; tamoxifen has been associated with an increased incidence of endometrial cancer. Toremifene, like tamoxifen, has been embryotoxic and fetotoxic in animals.

DRUG INTERACTIONS—Drugs that induce CYP3A4, such as phenytoin *(Dilantin,* and others) or carbamazepine *(Tegretol,* and others), lower serum concentrations of toremifene. Drugs that inhibit CYP3A4, such as ketoconazole or erythromycin, may raise them. Like other antiestrogens, toremifene may increase the prothrombin time in patients taking warfarin.

LETROZOLE—In postmenopausal women, estrogen production arises mainly from peripheral conversion of adrenal androgens to estrone and estradiol, catalyzed by the enzyme aromatase (estrogen synthetase). Selective aromatase inhibitors such as anastrozole decrease estrogen biosynthesis. Aminoglutethimide is a less selective inhibitor of steroid synthesis and must be given with a corticosteroid. Letrozole (let′ roe zole), a dibenzonitrile derivative, is a selective inhibitor of aromatase.

Pharmacokinetics—Letrozole is completely absorbed from the gastrointestinal tract, metabolized in the liver, and excreted mainly in urine, with a half-life of about two days.

Clinical Trials—A randomized trial in 551 postmenopausal women with advanced breast cancer that had progressed despite antiestrogen therapy compared 2.5 mg/day of letrozole with 160 mg/day of megestrol acetate. The response rate was higher (23.6% *vs* 16.4%) and the median survival was longer (770 days *vs* 655 days) in patients taking letrozole (Dombernowsky P, et al, *J Clin Oncol* 1998; 16:453). Another large randomized trial compared letrozole (0.5 or 2.5 mg/day) with aminoglutethimide 250 mg bid. (a lower dose than usual); response rates were 17.8% with letrozole 2.5 mg/day, 16.7% with letrozole 0.5 mg/day and 11.2% with aminoglutethimide. The median survival of patients taking letrozole 2.5 mg/day was 792 days compared to 592 days in patients taking aminoglutethimide (Possinger K, et al, *Ann Oncol* in press). No controlled trials are available comparing letrozole with anastrozole.

Adverse Effects—The most common adverse effects of letrozole have been musculoskeletal pain and nausea. Headache, arthralgia, fatigue, dyspnea, cough, vomiting, constipation, diarrhea, and hot flashes have occurred. Peripheral edema, anorexia, and weight gain have been reported. The rates of thromboembolic events, vaginal bleeding, and weight gain have been lower with letrozole than with megestrol acetate. Although not studied in pregnant women, letrozole has been embryotoxic and fetotoxic in animals. No drug interactions have been reported.

CONCLUSION—Toremifene is a new antiestrogen that offers no demonstrated advantage over tamoxifen for treatment of breast cancer. Letrozole is a new aromatase inhibitor for treatment of advanced breast cancer in postmenopausal women with disease progression despite antiestrogen treatment. Early studies suggest that it may be more effective than megestrol acetate or aminoglutethimide; it has not been compared to anastrozole.

‘On Machine’:
His Doctors Avoided the Dying Patient’s Agony

MAUREEN MALLOY D’HONAU

THE doctor asked the question and waited. Words: I counted them.

From the doctor there were six: “Do you want him on machine?”

From my husband, Charlie, there had been three: “I can’t breathe.”

From me there would be one: “Yes” or “no.”

“No” meant watching Charlie suffocate. How could I choose that? What fate had delivered the sentence to me?

“Yes,” however, must mean an ominous procedure. What kind of machine? Why had I not been prepared for this? Wasn’t there another option—a medical way to relieve his agony and terror?

I’d been given a Sophie’s Choice. For an instant, in fact, I saw the scene as a still shot from a film—the tall doctor and his emergency team, the nurse, and the patient in the unforgiving hospital light.

They all looked at me silently. I needed time. I needed them to give me a minute. Just a second.

I must explain that Charlie and I had promised each other never to allow extraordinary medical procedures. No life support. We’d been married more than 40 years. I couldn’t let anyone hurt him.

There was the click of the minute hand from the wall clock. In 15 minutes, unless I said “yes,” Charlie would be dead.

“Best medical care”:

This long day’s odyssey began when I called the cardiologist at home to tell him Charlie had awakened somewhat disoriented and with signs of a cold. The cardiologist was a member of “Charlie’s Medical Team.” This team was formed in early 1994 when Charlie’s previously diagnosed emphysema went from mild to severe, impacting his already damaged heart.

Protected by a generous medical insurance plan (not an HMO), we decided to find the best medical care in the Bay Area. Impartial medical authorities steered us to the UC-San Francisco Medical Center.

“Arguably, the best in the West,” we were assured.

And then, with the highest recommendations, we selected a distinguished senior internist (our primary doctor), a cardiologist, and a pulmonologist.

For almost three years, with regular and frequent visits to these doctors, Charlie was carefully monitored. Despite living with the cruel realities of irreversible and progressive illness, we felt fortunate. Between us and the horrors of dehumanizing, high-tech medicine, we had our personal, expert medical team.

The emergency room:

Our cardiologist told me to bring Charlie to the hospital’s emergency room and, totally trusting his judgment, I followed directions.

Yet, on this day, no member of the team was in the emergency room where Charlie was kept for 10 hours.

The 10-hour ordeal clearly led to the breathing attack and the doctor’s question.

Charlie is gasping. Do I say “yes” or “no”?

I said “yes,” and I never heard Charlie’s voice again.

Intensive care, Day 1:

Very early the next morning, admitted to the intensive care unit, I saw Charlie “on machine.” It was a respirator or ventilator, a long tube inserted in the mouth and down the throat to the lung. It was kept in place by a piece of tape stretched across the face like a gag.

MAUREEN MALLOY D’HONAU, a *San Francisco Examiner* contributor, a San Francisco realtor, and was for many years a columnist for the *Japan Times*. Reprinted with permission, from the *San Francisco Examiner*, Wednesday, 5 November 1997, A23, by the author Maureen Malloy D’Honau.

Charlie was awake and in obvious anguish. When he saw me, he lunged in a futile attempt to rid himself of the tube and other lines. His hands were tied to the bed.

A doctor was nearby, and I told him that Charlie, in the last year with his increased breathing problems, had developed acute claustrophobia. Any feeling of enclosure or restraint sent him into a panic. Could he be given more sedation?

The doctor said that with a goal of removing the respirator, Charlie could not have much sedation as it would relax the lungs, decreasing his breathing capacity.

I turned to Charlie, who was looking at me desperately.

"Please don't panic," I begged. "I'm going to call the internist—you know his office is just across the street. He'll be right over."

I was confident that once the internist was on the scene, Charlie's suffering could be relieved. He was the captain of our team, our trusted medical friend.

Eleven hours after my call, at 7 P.M. that night, the internist arrived. I described the lunging periods. The sedation seemed to last about 45 minutes, followed by 15 minutes of Charlie's vain struggle.

Despite his hands being strapped down and my gentle restraint, he had managed to dislodge the tube and pop some of the other lines.

Emphatically, I said, "I don't want him to suffer."

The internist very quickly explained that his visit was strictly a courtesy call.

"You see," he said, "when a patient is in intensive care, only the attending doctors are in charge." (These doctors are interns or residents headed by a senior specialist who rotates each week. They make their rounds twice daily.)

Then, in parting—after about five minutes—our former internist offered what he called "an important tip":

He said "intensive care" does not always mean one-on-one nursing care. The nurses often care for two or three critically ill patients at one time. He suggested that if I were strong enough I should stay around the clock, because Charlie needed constant attention.

He left. I stayed.

Never before had I experienced such a feeling of being abandoned. I felt weak and helpless, like a child who has lost his parents. The medical support I had built and nurtured for three years had vanished. Charlie had become a numbered patient, institutionalized in a huge teaching hospital, albeit with full insurance coverage.

Not a word of comfort or compassion had come from our doctor. I remembered doctors past. There was Dr. Fugi during our Tokyo years who showed as much concern for the family as the patient. And dear Dr. Unger in New York City who was available by phone seven days a week. His patients would swear he loved them.

As the night wore on, the lunging periods seemed longer and more unbearable. I had to look into Charlie's pleading eyes.

Finally, I asked the nurse to call the doctor on duty to observe and possibly increase sedation. (Could more sedation be worse than these crazed and hopeless struggles?)

The duty doctor came and, seeing me in a corner of the room, asked the nurse who I was. (Presumably, I could not identify myself.)

The nurse answered, and he said loudly, "Get her out." He did not increase the sedation.

Clearly, I could not depend on the kindness of medical strangers. Some would stereotype me as a potentially hysterical, medically ignorant, general irritant. Yet, I was now Charlie's only voice. Was it only a few years ago that as publisher of its Asia edition, Charlie had been called "the voice of *Time* magazine"?

But I must stay in the present. I thought of a line spoken by Mrs. Willie Loman about her sick husband in Arthur Miller's "Death of a Salesman."

She said, "He is a human being. Attention must be paid."

As a coping device, I decided to create a sympathetic character role for myself in our own life-and-death drama. I named my character The Sycophant. This character would please, flatter, even fawn if necessary.

Days 2 to 14:

The UC-San Francisco intensive care nurses are on 12-hour shifts. Most are not permanent members of the staff. There is little continuity. Rarely did Charlie have the same nurse twice.

I was there 15 to 16 hours a day and tried to blend into that strange, artificial world without natural light or color except for the "scrub" outfits worn by the nurses.

By assuming the role of The Sycophant, I was able to stifle sarcastic or bitter replies to well-meaning but sometimes insensitive remarks.

At least once a day a doctor and/or a nurse told me that intensive care is the most dangerous place for a patient—full of deadly germs.

One time, a senior pulmonologist making his rounds saw Charlie awkwardly tugging at the respirator. Standing over the bed, he said, "A respirator is torture. I couldn't stand it."

Then there was the day a spinal tap was strongly recommended. I hesitated; another assault to the body. So the doctor told me a reassuring "true" story about a spinal tap done on an elderly male patient. Syphilis was discovered, and the man made a full recovery.

Day 15:

The respirator was removed. Charlie couldn't talk or swallow.

Day 16:

One doctor discussed the merits of doing an angiogram. Later, another doctor told me Charlie was dying. Later, a third doctor told me Charlie would have to be moved to a rehabilitation facility.

Days 17 and 18:

All agreed that Charlie would die soon. I was reluctant to leave at night, though he was sleeping most of the time. The nurse encouraged me to go home for a few hours. She promised to call if I were needed.

Day 19:

I returned to the hospital at 7 A.M. Seeing Charlie sleeping, I mentioned to the nurse that he must have had a peaceful night.

"Actually," she said, "Charlie had a bad time around 4 A.M., and I asked him if he wanted me to call you."

He shook his head no.

I wanted to scream at her betrayal, but The Sycophant made no reply. That lost and last moment of being with Charlie in his suffering is a burden of sorrow I shall carry always.

During this day, Charlie went into a deep "sleep."

Day 20:

At 6 A.M., I called the night nurse from home to see if there was any change. She said cheerfully, "He looks like a million dollars. I shaved him and gave him a bath."

Charlie died at 7:45 P.M. It took him three weeks.

Two weeks later.—Our internist, the former primary doctor, called to ask me how Charlie was doing. I told him Charlie had been dead two weeks.

"Oh," he replied. "The hospital listed him as discharged, so I had no way of knowing."

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◆ Referrals to the **Physician Health Program** are confidential, and experienced help is only a phone call away.

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Neil J. Grey, M.D.
Medical Director

Michele R. Norbeck
Director

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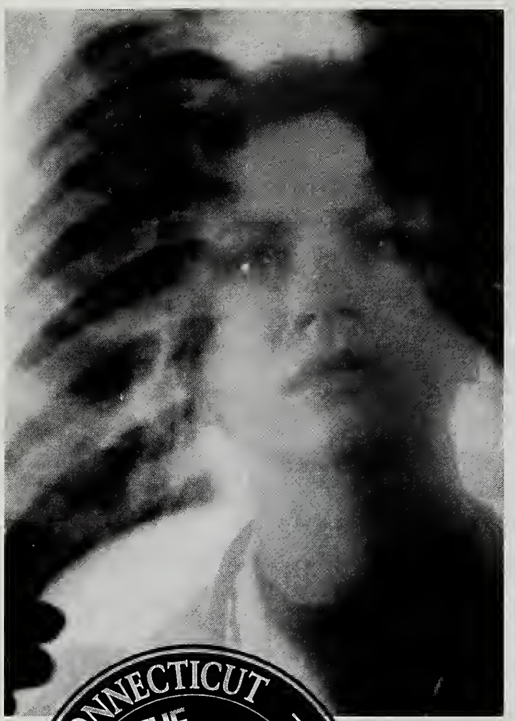

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and D.O., Doctor of Osteopathic Medicine

Commentaries

“A Close Look at Therapeutic Touch”

In its 1 April issue, *JAMA* published an article “A Close Look at Therapeutic Touch,” refuting an important premise of therapeutic touch. Many of us read the article, many more read about it in the *New York Times,* heard about it on NPR, or saw it reported on the evening news. Its conclusion was unambiguous: Twenty-one experienced TT practitioners were unable to detect the investigator’s “energy field.” Their failure to substantiate TT’s most fundamental claim is unrefuted evidence that the claims of TT are groundless and that further professional use is unjustified.

The Hartford Courant initially ignored the story apart from a mention the following week on its kiddie page. (The *Courant* liked the fact that a child was one of the coauthors.) Piqued by this omission, I started paying more attention to the *Courant*’s health and science coverage, and I’ve been dismayed by what I’ve seen—an example statement that “Echinacea, chamomile, and ginseng are as common in home medicine cabinets as aspirin and cough medicine;” an article about exercise audio tapes for drivers, headlined “Work Out! It’s Chic—While Driving;” the statement, in an article about experiencing breast cancer, that journalists “make the worst patients. We have a need constantly to seek information *we aren’t supposed to have.*” (Emphasis added.)

As a former practicing physician and current medical librarian, I am particularly angered by the last example, because the implication that doctors in general wish to withhold medical information from their patients seems terribly wrong headed and behind the times. In actuality, most physicians I know seem to wish that their patients were better informed, and perhaps even hope that journalists might help in the effort to bring this about. Some journalists already do: Lawrence K. Altman and Jane E. Brody are examples. However, “The Oldest Continuously Published Newspaper in America” is doing a much less adequate job of letting people know what some of the medical issues are than the *New York Times*, and the *Hartford Courant* has a much greater circulation in Connecticut.

Whenever I see one of those monstrously trivial articles in the Health&Science section of the *Courant,* I see not only the silly article (“LIVE LONGER! All It Takes Is A Better Monogram!”), but the useful and interesting article that could have been there instead. All of *Connecticut Medicine*’s readers are likely to have medical topics they would nominate for thoughtful and accurate coverage in Connecticut’s most widely read newspaper.

I am frustrated by seeing an upsurge of interest in alternative medicine with so little real medical information available to the average newspaper reader to counteract it. I would hope that those who cover medical topics at the *Hartford Courant* would learn more about what the important medical issues are, and how to access and report reliable information about them. Anyone with internet access now has press access to virtually unlimited medical information on the World Wide Web, including Medline via PubMed or Internet Grateful Med. Those covering medical subjects for the *Courant* need to learn how to use and interpret these resources.

I would like to ask the readers of *Connecticut Medicine* to call the *Hartford Courant* suggesting that they cover current medical issues adequately. The *Courant*’s readers’ representative is Elissa Papirno, phone number (860) 241-3900, e-mail: readerep@courant.com. If we fail to react, nothing will happen. The same pap will continue to be presented week after week.

Ann Merriol Almond, M.D., M.P.H., M.L.S.
West Hartford

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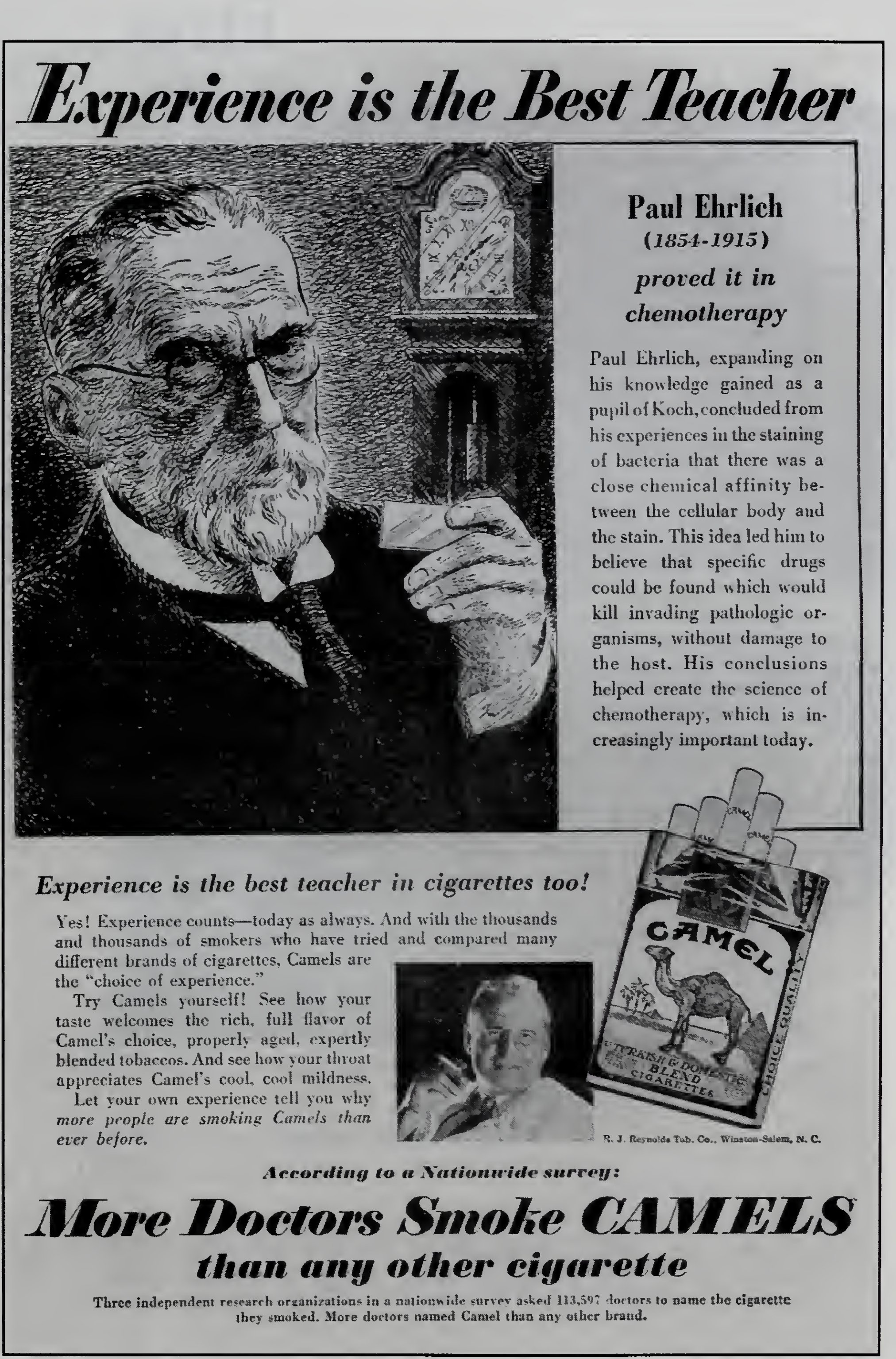
50 Years Ago

From *The Connecticut State Medical Journal*

June 1948



Experience is the Best Teacher

Paul Ehrlich
(1854-1915)
proved it in chemotherapy

Paul Ehrlich, expanding on his knowledge gained as a pupil of Koch, concluded from his experiences in the staining of bacteria that there was a close chemical affinity between the cellular body and the stain. This idea led him to believe that specific drugs could be found which would kill invading pathologic organisms, without damage to the host. His conclusions helped create the science of chemotherapy, which is increasingly important today.

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Reprinted from the *Connecticut State Medical Journal*, June 1948.

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- Pediatricians
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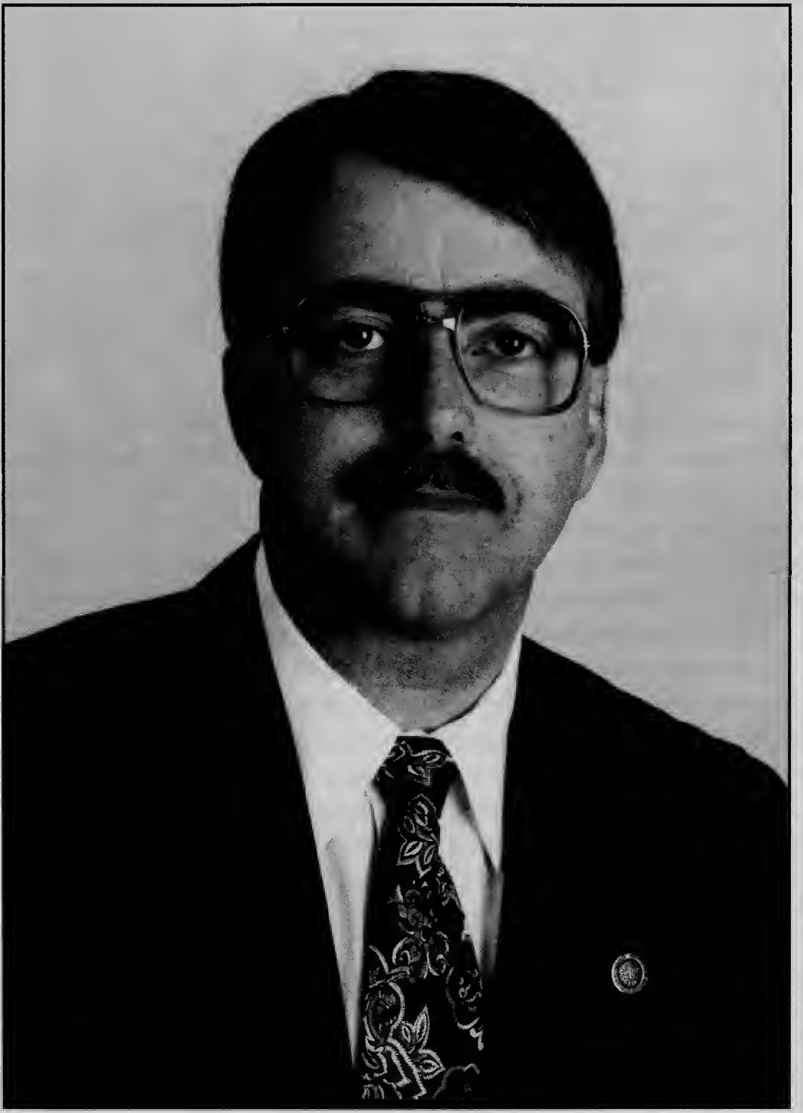

Craig W. Czarsty, M.D.
PRESIDENT

CRAIG W. CZARSTY, M.D..

Education:

1971	Canterbury School, New Milford, Connecticut
1975	Georgetown University, B.S., Biology
1980	Georgetown University School of Medicine, M.D.
1983	Roanoke Memorial Hospitals, Roanoke, Virginia, Family Medicine Residency

Board Certification:

1981	Diplomate, National Board of Medical Examiners
1983	Diplomate, American Board of Family Practice

Fellowships:

1986	Fellow, American Academy of Family Physicians

Medical Licensure:

1981	State of Virginia
1983	State of Connecticut

Board of Directors:

1996-	Physicians Care for Connecticut, Inc.—Founding President-Chair of the Board, 1996
1995-	Health One Connecticut, P.C.— Founding President, 1995

Professional Experience:

1983-	Private Practice, Family Medicine, Oakville, Connecticut
1983-	Clinical Assistant Staff, Department of Family Practice, St. Mary's Hospital, Waterbury
1983-	Department Surgeon, Watertown Police
1983-	Department Surgeon, Watertown Fire Department
1983-	Assistant Medical Examiner, State of Connecticut
1983-	Waterbury Hospital, Assistant Attending Staff, Medicine, 1983-1984 Assoicate Attending Staff, Medicine, 1984-1986; Attending Staff, Medicine, 1986-; Emergency Room Physician, 1983-1986
1983-	Medical staff, Grove Manor Nursing Home, Watertown Convalarium, Medical Director, 1987-
1986-	Line Physician, Metro North Railroad
1984-	State Police Surgeon, Connecticut Department of Public Safety
1984	Team Physician, Waterbury Angels (AA Farm Club of California Angels)
1985-1986	Team Physician, Waterbury Indians (AA Farm Club of Cleveland Indians)

Professional Organizations:

1978-	American Academy of Family Physicians—Delegate from Connecticut, 1997-
1978-	Connecticut Academy of Family Physicians—President, 1989-1990, 1992-1993
1992	Connecticut Managed Service Organization—Incorporator,1992; Secretary-Treasurer, 1992-95
1983-	Waterbury Academy of Family Physicians
1980-1983	Virginia Academy of Family Physicians
1983-	Waterbury Medical Association—President, 1989
1984-	New Haven County Medical Association—President, 1994-1995
1984-	Connecticut State Medical Society, President, 1998-1999; President-elect, 1997-1998; Vice President, 1996-1997; Associate Councilor, 1995-1996; Chairman of Bicentennial Committee, 1990-1992
1994-	Connecticut Medical Insurance Company—Claims Committee
1995-	MedServe of Connecticut, Inc.—Founding President, 1995
1984-	Member—American Medical Association
1986-	Waterbury Independent Practice Association—Charter Member

Editorial Committee:

1995-	American Family Physician—Editorial Board
1988-1997	*Core Content Review of Family Medicine,* Executive Committee

The Challenge of Change

The next decade will be a time of difficulty and change for the medical profession and for our medical associations. The winds of change are blowing, and they will blow on the prepared and unprepared alike. Our cottage industry is transforming itself into systems more integrated and business-like. The mechanism of this transformation is consolidation, and consolidation is what I would like to speak about today. I will begin by presenting portions of the Report of the Council on Long Range Planning and Development to the interim meeting of the American Medical Association's House of Delegates in Dallas in December 1997. I will then discuss how the consolidation of the practice of medicine will affect the CSMS.

Medicine is neither the first nor the last service industry to undergo a consolidation. We have seen it happen to banks, real estate companies, and hospitals. Consolidation is a response to disequilibrium in market forces. It is driven by various mechanisms. Technologic advances in computers and telecommunications drove the consolidation of the real estate industry. Changes in legislation or regulations such as the congressional decision to allow interstate branch banking have resulted in some very large regional and nationwide banks. Changes in consumer preferences also play a large part in forcing consolidation. Hospitals are a good example. Not too long ago, payors simply footed the bill for whatever the hospitals charged. Payors now exert leverage on the hospitals to extract the maximum discounts possible. The hospitals are responding by integrating into systems to exert counter leverage.

Consolidation of the health-care industry will have many effects on physicians. Some will be welcomed, and others not. The change that physicians will probably appreciate most is a more healthful work environment. Many of the quality-of-life issues will improve as physicians move into employee roles. They will work shorter hours, take fewer calls, and be able to concentrate more on the clinical aspects of practice rather than the business aspects. As employees, they will enjoy health insurance, paid vacation, and time off for continuing medical education.

The quality of care for patients may improve if health systems have the resources to develop good outcome measures. The health systems can then truly compete on the basis of documented quality of care.

However, the physician-patient relationship may decline as physicians move into employee roles and begin to enjoy their new lifestyles. Shorter hours and fewer calls mean patients will have more difficulty reaching their own physician. Health systems may aggravate this problem with the use of midlevel providers which will further limit access to physicians.

Declining clinical autonomy may be expected as the industry consolidates. Health systems will use outcome measures to define "best practices," and they will strongly encourage physicians to follow the guidelines. The encouragement will be both peer pressure and economic incentives and disincentives. Health systems will shift resources to services with high-revenue margins and discourage physicians from performing services with low-revenue margins.

Medical ethics are also at risk. Consolidation into health systems could lead to a situation in which the ethics of an individual physician are supplanted by the ethics of the organization for which the physician works. The risk is that the whole value system of the medical profession fundamentally could change.

Experience with consolidation in other industries suggests that competition will increase and will be intense. In our case, lack of capital will mean that solo and small group practitioners will find it increasingly difficult to compete with large groups and institutional practices. Solos and small groups will not disappear, but they will be forced into niche markets as were small, home-town banks when the large banks came to town.

As more physicians are moving into employee roles, there will be increased interest in so-called "physician unions." Physicians will seek ways to prevent the erosion of their clinical autonomy and erosion of their compensation. We have already begun to see signs of this in Connecticut.

As the practice of medicine consolidates, economic pressures on our medical associations will intensify because the typical association will experience a decline in membership for a number of reasons. Stagnant or declining physician compensation will make members increasingly resistant to dues increases, and they will limit the number of associations to which they belong. Employed physicians will see limited value in the traditional products and services of medical associations. Health systems will be reluctant to pay association dues for their employees, as the aggregate will be a large line item in their budgets. New special interest associations will emerge to meet specific physician needs.

An example is the American College of Physician Executives. These new associations may be specialty-like societies or they may look and act like unions.

In Connecticut, we have been fortunate to be insulated from declining membership in our state and county societies. Several physician-founded companies continue to require society membership as a prerequisite of participation. However, unlike Blanche in *A Streetcar Named Desire*, we cannot depend on the kindness of others. Economic pressures on those companies could lead their boards to remove the requirements of society membership. Those boards have a fiduciary responsibility first and foremost to their respective companies.

The report of the Council on Long Range Planning and Development concluded, "The Federation of Medicine as it exists today, with large Houses of Delegates and expensive policy-making processes, will not survive the "shakeout" that will occur in the medical association sector." It also predicts that some associations will fail and cease to exist while new societies and a new federation may emerge. The report also makes a strong argument for the Federation Coordinating Team of which our own executive director is a member.

What, then, are the implications for the CSMS of consolidation in the medical industry? There are many, but I would like to address four of them: implications for the House of Delegates, collective bargaining, advocacy, and dues income.

Most of you completed a poll at the semiannual meeting regarding the format of these meetings. The majority of you indicated satisfaction with the meetings and preferred not to make any substantive changes. This level of satisfaction is not borne out by the fact that most of the members will have left before the closing gavel. Perhaps we asked the wrong questions in the poll. I believe it is time to start debating among ourselves whether it is time to look at the basic structure of the House. The California Medical Association restructured its House to allow for representation of group practices and specialty societies. The AMA itself is increasing specialty representation. We have to make a concerted effort to bring residents and students back into the House. Our by-laws allow them to be seated, but we are not doing a good enough job attracting the future doctors of our society to join us. Perhaps the most basic question of all is whether or not we even need a House of Delegates anymore. Could the smaller, easier-to-convene Council run the Society more efficiently? I urge you to take these questions back to your counties, discuss them, and bring back any resolutions you feel appropriate.

Another question facing this Society, like it or not, is whether it is time to investigate the provision of collective bargaining for our employee members. The California Medical Association has done just that, and the California Association of Interns and Residents has approached the CMA about a possible alliance. The U.S. Congress is considering a bill that would allow medical associations to bargain for its members. I am certainly not suggesting we turn the CSMS into a union, but I am suggesting we look at creating an entity, owned by us, which would be able to bargain collectively. I believe that failure to address this issue will be the biggest threat to membership recruitment and retention in the future.

The advocacy arena has been one of the biggest success stories of the CSMS. Even with shamefully low membership in COMPAC, we have been amazingly successful in the state legislature. Unfortunately, advocacy is going to be one of the most problematic areas in years to come as more physicians become employees. Issues that we mostly agree on now will not have that same agreement. For example, large groups and health systems may very well not want us advocating "any willing provider" legislation because it might not be in their own best interests. How long can we cast aspersions on capitated contracts when most of our members are having to work under them, and some are prospering under them? I suggest that the focus of medical advocacy will have to be on preserving the physician-patient relationship. Concurrently, the CSMS must establish itself as the arbiter of medical ethics in this state.

Lastly, we must vigorously investigate means to reduce the pressure on the dues dollar. We should look for ways to cut costs and look for ways to increase nondues revenues. We will have to determine what products and services physicians will need. It is important to realize that we must individualize those products and services. One size will no longer fit all. Different members or groups of members will need us for different things.

Getting the CSMS ready to compete and win in the next century is a major undertaking that will take, in my opinion, three to five years of hard work, starting now. It will require the best efforts of us all, volunteers and staff, and will probably involve some outside expertise. I believe we need to do some strategic planning with the goal of prioritizing the tasks we face and deciding what resources we need to accomplish those tasks. No association can survive if it doesn't have a clearly defined mission.

I am sure that by now most of you have seen the movie, *Titanic*. We all know what happened back in 1912. The largest, most modern vessel ever built steamed at full speed into iceberg- laden waters, ignoring warnings and with poorly equipped lookouts. At the helm was a skipper nearing retirement with a lifetime of experience commanding ships at sea. The lesson to be learned from the sinking of the Titanic is that of hubris, the willing suspension of disbelief. No ship is unsinkable, and, in the crisis, the captain's skills were of little use, as the only experience he had never had up until that day was to stand on the decks of a sinking ship.

Let us take care that we are not guilty of hubris, too, and thereby allow the CSMS to founder. We are sailing into the uncharted waters of change. We have a leadership structure with a wealth of experience, but no one, not one of us, has ever dealt with the forces of consolidation such as we see headed our way. Past experience will be of limited use. The skills that will be required are the abilitiy to anticipate change and to make plans to deal with it.

In ancient Rome, there was a group of men known as the "boni." The boni were an ultraconservative faction within the Senate. While they cherished Rome and its traditions, they fiercely fought any departure from tradition. Ultimately, they unwittingly contributed to the downfall of the Republic and the rise of the Empire. Let us guard against the development of a boni-like clique within the CSMS. While change for change's sake alone is not healthy, neither is unyielding resistance to change.

The challenges facing organized medicine are many, the solutions will be varied, and they will originate from several sources. The House of Medicine in Connecticut and beyond must put aside the political considerations and jealousies of the past. To paraphrase George Will, we must not huddle together for warmth in the clean, well-lit prison of one idea. For the Federation to survive, each Association must respect the others' strengths and be willing to help those in need. First and foremost, though, we must refocus on the physician-patient relationship.

I would like to close by thanking this House for the trust you placed in me by electing me president. I look forward to working with all of you. My door will always be open, and I welcome your input.

Craig W. Czarsty, M.D.
President

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In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

Name of person filing the concern or complaint:

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Address: ____

Phone where the Department can contact you: (_____) ______________________________

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Policy Number: ____

Name of Policyholder: ____

Name of Enrollee: ____

Name of Patient: ____

Patient is ___ self ___ dependent ___other (explain)______________________________

The following is a detailed description of the concern or complaint:

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REFLECTIONS ON MEDICINE

Neutrinos, the Mind, and the Theory of Everything

ROBERT U. MASSEY, M.D.

EARLY this month the Hartford *Courant* carried an article announcing that "Finding About Neutrinos May Solve Cosmological Question." According to physicists at the Super-Kamiokande detector in Japan, neutrinos oscillate and therefore must have mass, enough perhaps that the expanding universe, rather than expanding forever, will slow its expansion, stop, and collapse back on itself. In my ignorance I had assumed that neutrinos had some mass even though they were the tiniest of particles, but apparaently there have been some physicists who thought them weightless. Stephen Hawking (1988) describes them as "extremely light (probably massless) ... affected only by the weak force and gravity." The *Courant's* writer then went on to quote a physicist to the effect that "These new results could prove to be the key to finding the Holy Grail of physics, the unified theory, or the Theory of Everything." I had known that as "GUT," or the "grand unified theory," that would explain all about mass and energy. and therefore about everything from the Big Bang to the human brain to the Big Crunch.

These three are by no means unrelated. The most recent issue of *Daedalus* (Spring 1998) is devoted entirely to the brain, and although *Daedalus* is the Journal of the American Academy of Arts and Sciences, the 11 articles would be considered watered down only by those working in neuroscience research, and, I suspect, by only a few of them. I recall a conversation with a neuroanatomist perhaps 15 years ago, during which he declared with conviction that the last quarter of this century and the first quarter of the 21st would be remembered as the golden era of the brain. We were nearly at the point of explaining it, he said.

The most challenging problem, according to the *Daedalus* contributors, is that of consciousness. Some years ago at Trinity College in Hartford, Nobel-prize winner Sir John Eccles gave a lecture on the anatomic basis of memory, and showed some remarkable electron microsopic slides of "climbing fibers" that grew as memory was formed. Afterward during a brief conversation with a neuropharmacologist friend and me, my friend asked, "Sir John, why didn't you mention The Problem?" "Not the right audience," he responded with a grin.

I could hear the capital letters and as we walked away, and I asked my companion what he had meant. "Consciousness, of course. How can atoms of carbon, hydrogen, oxygen, nitrogen, potassium, sodium, calcium, chlorine, phosphorous, and a few other elements assemble themselves into an amoeba, or dog, or you and me, and, what's more, could think, could look into a mirror and say 'that's me,' could write a sonnet, a Bach cantata, or conceive of the theory of general relativity, and then reproduce itself to boot? Not only that, but then the whole universe is highly improbable!"

Even more improbable is the brain. Gerald M. Edelman, a contributor to the *Daedalus* papers writes:

> The brain of an adult human is about three pounds in weight. It contains about thirty billion nerve cells or neurons. The most recently evolved outer corrugated mantle of the human brain, the cerebral cortex, contains about ten billion neurons and one million billion connections, or synapses. Counting one synapse per second, we would just finish counting thirty-two million years from now. If we consider the number of ways in which circuits of loops of connections could be excited, we would be dealing with hyperastronomical numbers: 10 followed by at least a million zeros. (There are 10 followed by seventy-nine zeros, give or take a few, particles in the known universe.)[1]

"What are the basic functions of the cerebral cortex," asks another author, Vernon B. Mountcastle, and he answers himself, "The direct answer to this question is that no one knows." And then he proceeds to list 16 generalizing principles of which we can be reasonably certain, most of which were the products of brain research developed in the last half century, one of which is "The view that all mental events are brain events." Yet these hardly begin to satisfy Isaiah Berlin's criterion of being "so general, so clear":[2]

> The ideal of all natural science is a system of propositions so general, so clear, so comprehensive, connected with each other by logical links so unambiguous and direct that the result resembles as closely as possible a deductive system, where one can travel along wholly reliable routes from any point on the system to any other.[3]

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

Edelman writes, "The greatest challenge to modern neuroscience is to provide an adequate explanatory basis for consciousness" which he defines as the "remembered present." Although we might all agree that consciousness is the *magnum mysterium,* most believe its workings will one day be reduced to neuroanatomy and neurophysiology. Edelman in one of his notes comments (p 69):

> I will also hazard a guess: as has been the case in other domains of science, once we know the facts and principles of brain function and structure more securely we will be able to imitate nature to a limited extent. At such time we will construct a conscious artifact. If we can give it the basis for language, we will be able to ask whether it categorizes or "carves nature at the joints" the way we do. The answer will perhaps provide as exciting or terrifying a prospect as hearing from intelligent life somewhere else in the galaxy. The ethical implications are obvious....

That conscious artifact, most authors agreed, would not resemble a computer, and one author, Andy Clark, writes of "the distance separating biological and 'engineered' solutions to problems." Engineers design, evolution tinkers, and the results are vastly different.[4] In the early years of computing machines, Alan Turing and others thought that ultimately these machines would become conscious, would know that they exist, and would know that they know! I wonder how we would know!

In the past, neuroscientists simply avoided the problem or wrote it off as insoluble. My neuroanatomy course 56 years ago was taught by a brilliant neuroanatomist; she never mentioned the mind, and described no anatomic basis for thought or perception or Freud's superego, ego, or id. Clark comments that "... even a full physiological story would not, in and of itself, reveal how brains work qua mind-producing engines."

Eccles resolved the consciousness problem by locating the mind outside the brain; to put that more simply, he refers to the "mind, or the self, and its brain." It is the "self" that is conscious, it is the "self" that uses its brain to process information. Like Plato and Descartes, Eccles is a mind-body dualist. The problem with that concept is that it violates one of the requirements of a good theory: it defies being proved wrong.

J.B.S. Haldane (1892–1964) in his book *Possible Worlds* wrote, "If my mental processes are determined wholly by the motion of atoms in my brain, I have no reason to believe that my beliefs are true ... and hence I have no reason for supposing my brain to be composed of atoms." Sir John Sherrington (1861–1952) won the Nobel Prize in 1932 for his work in neurophysiology at Oxford. In 1946 in his book, *Man on His Nature*, he asks "Has the evolution of the brain produced mind out of no mind?" (p 261) "But we have seen that evolution does not create. All it does, out of something which was, is to construct something further." (Tinkering?) He continues:

> A brain-cell is not unalterably from birth a brain-cell. In the embryo-frog the cells destined to be brain can be replaced by cells from the skin of the back, the back even of another embryo; these after transplantation become in their new host brain cells and seem to serve the brain's purpose duly. But cells from the skin it is difficult to suppose as having a special germ of mind. (p 272)

Sherrington whom Wilder Penfield called "sensitive schoolboy, sturdy athlete, traveller, lover of art, investigator, teacher, scholar, raconteur, many-sided genius—Physiologist, Philosopher, Poet," described thought as a thing repudiated by natural science, "something outside its ken." Is this mid-20th century's remnant of vitalism? And are neuroscientists, cognitive scientists, about to refute it? Some (most?) of them are optimistic enough to believe so.

Sometime about 90 years or so ago, Ambrose Bierce (1842–?1914) defined mind:

> MIND, n. A mysterious form of matter secreted by the brain. Its chief activity consists in the endeavor to ascertain its own nature, the futility of the attempt being due to the fact that it has nothing but itself to know itself with.

In *The Wisdom of the Body* Sherwin N. Nuland writes of his "conviction that the human spirit arises from the physiology of the human body, just as does the mind of which it is a product."[5] It yet remains, I believe for most of us, the *magnum mysterium*, perhaps, in spite of the optimism of the cognitive scientists, forever incomprehensible. But watch out for that conscious artifact!

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MEDICAL NEWS CAPSULES

This Month's Reading in Review

TIMOTHY B. NORBECK

California Governor Pete Wilson has proposed the creation of a new Department of Managed Health Care, which would assume the managed-care regulatory functions currently held by the state Department of Corporations.... "This reorganization plan is a fundamental first step towards ensuring that government keeps pace with the enormous changes occurring within the health care industry."...The plan will go into effect 1 July 1999, "unless one house of the Legislature rejects the proposal."

National Journal (4 May 1998)

"It's time to put up or shut up. Either the HMOs don't have a lot of money and shouldn't pay these high salaries to their CEOs, or they do have a lot of money and shouldn't oppose managed care regulations."

A New Jersey Citizen Action release criticizing HMOs for opposing managed-care regulations.
American Medical News (27 April 1998)

"This is an issue we will ignore at our peril, come November. Some of the Republican leaders are like the little Dutch boy with his finger in the dike. They are trying to hold it back. But popular sentiment across America says we need to do something, and the pressure will increase every day that goes by without action by Congress."

New York Representative Michael P. Forbes (R) commenting on the need for managed-care reform. *New York Times* (11 May 1998)

"Public anger over the state of managed care has burst into this yearís election campaigns as a major issue, up there with perennials like education, crime and Social Security." In at least a score of states, including New York, California, Texas, Florida, and North Carolina, candidates in primaries and general elections for governor and Congress typically are promoting access to more doctors, a right to appeal managed-care organizations' decisions on restricting care to impartial tribunals, and freedom to sue the organizations for malpractice.

New York Times (17 May 1998)

A blind graduate from Notre Dame University will become the "second blind person ever admitted to a U.S. medical school."... This fall, Timothy Cordes will enroll at the University of Wisconsin's medical school.... He plans a career in research.

Washington Post (18 May 1998)

- Number of times paperwork received each year by the IRS would encircle the Earth: 36
- Percentage of the IRS's own budget for which it could not account in 1993, according to a General Accounting Office audit: 64%
- Number of trees that must be cut down each year to supply the eight billion pages of paper needed for filing the country's income taxes: 293,790
- Number of times the IRS gave the wrong answer to taxpayers seeking help to comply with the tax code in 1993 (taxpayers are still liable for errors caused by bad IRS advice): 8,500,000.

From Daniel J. Mitchell's "577,951,692,634 Reasons.... and Counting: Why a Flat Tax Is Needed to Reform the IRS" and published in *The American Enterprise* (May/June 1998)

Thank You Very Little, Mr. Carrier

"Who do we really blame for the Washington, DC, bureaucracy? Some people claim it's Willis Carrier who, in 1902, invented the air conditioner.... Until then, Federal workers used to be sent home whenever the temperature-humidity index topped 90 degrees.... But after air conditioning invaded our nation's capitol, keeping the city's famously hot summers at bay, federal bureaucracy mushroomed."

Newsweek special December issue 1997

Americans will soon be able to help fight breast cancer by paying extra for postage.... The Postal Service's Board of Governors yesterday decided that a first-of-its-kind breast cancer stamp will costs $.40, with the $.08 above the $.32 first-class mailing rate going to support research efforts.... The stamp is set to be unveiled this month and will go on sale in August.

Richmond Times-Dispatch (8 April 1998)

Only in America: A defendant, on trial for bank robbery in Oklahoma City, had attempted various times to demonstrate his incompetence to stand trial, but the judge had resisted the plea—including the incident when the defendant stood up, dropped his pants, and urinated on his lawyer.... A federal appeals court ruled that "incontinence does not equal incompetence," and affirmed the conviction.... The judge then lamented lawyers who "believe a law degree is that ticket to a glamorous career."

Chuck Shepard (19 May 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

"All Politics Is Local"

Letter to the Editor: Tip O'Neill knew what he was talking about when he said "All politics is local." It was his keen appreciation of this concept that allowed him to achieve the speakership of the House of Representatives.

The membership of the Connecticut State Medical Society is fortunate to have an active, effective legislative program under the able direction of David Parke, M.D., his Legislative Committee, and Mag Morelli. We also benefit from the efforts of our professional lobbyists, Sullivan and LeShane. In 1997, the passage of the Managed Care Bill, one of the toughest in the nation, was a major victory for CSMS. In the legislative session just ended, the CSMS's success in getting unanimous, bicameral endorsement for a "managed care prompt payment bill," *after it had been killed in committee,* is a crown jewel of which we can be very proud. But even with the highly professional efforts made at the state level, many of these victories would not have been achieved without the direct effort of our county medical associations, and their membership.

In the last analysis, it is the *individual physician* who makes the difference. You do this when you speak about an issue with your local legislator at the weekly Kiwanis luncheon, at the social hour after worship services, at a party where the two of you relate as friends and not merely as a voter to an elected official. You further these efforts when you can call your legislator at home *because you have been willing to exchange home phone numbers,* and you have invited each other to call whenever help is needed. When you take these actions, the legislator no longer sees "a doctor issue," or "a managed-care issue." He sees the concern of a local constituent, a neighbor, a friend! That is what makes the difference.

When you then bring these personal efforts to the county medical association, *the association can effectively coordinate the local, personal efforts of friends working with friends. It is through the county medical associations that unified, local efforts can be developed and perfected.* Repeat contacts can be made as necessary. "Friendship gaps" can be identified and filled. Through county legislative committees, and county annual legislative dinners, these efforts become united, implemented, and successful. The fruit of these labors can then flow upward to the final, CSMS coordinated statewide activity. It is then that the separate parts become whole in a single, statewide effort which is energized *and enhanced* by the efforts of its constituency, the county medical associations! That is the effective route to legislative victory.

So when you see something happening in the political arena that concerns you, *do worry, be active, get local!* Tip O'Neill knew what he was talking about!

Stephen R. Katz, M.D.
Fairfield

In Response to Dr. Bentivegna's Commentary
The Need for Single-Payer Catastrophic Health Insurance

I applaud Dr. Bentivegna for his commentary *The Need for Single-Payer Catastrophic Health Insurance* (*Conn Med* 1998; 62:237–40). It does seem logical to extend Medicare to all Americans. Let us join to eradicate business from medicine, and get back to caring for patients, to the intensive caring they need. Let us be able once again to celebrate the joy of our profession, rather than "battling byzantine bureaucracies." We should be able to recommend medicine as a profession with an open heart to young men and women willing to work on behalf of others. Every crusade requires demons, and Dr. Bentivegna names those who rape the system for obscene profits, extracted from the backs of human misery. The technological-industrial complex has made it impossible to go back to old arrangements. Medical care is far too costly, especially for the poor. Who can afford the cost of pills, visits to the ER, a passage through an ICU? Not 41 million uninsured Americans; the great majority of Americans die in hospitals, insured or not.

Let us return to the reasons we became physicians in the first place. I was a boy of 10 when Dr. Wallace made house calls to care for my mother's heart condition. His gentle ways set him apart. Ten years later he wrote my recommendation to medical school. He told me medicine is a calling. While a medical student, a great surgeon, Dr. Welch, gave me the key: "Just remember, the surgeon is a body servant." That humility has served me well as a surgeon since. It matched the gentility I learned as a boy from our general practitioner. Let us recreate medicine as the calling it ought to be. We can do it. No one else can.

Charles W. Needham, M.D.
Norwalk

The Ethics of Organ Transplantation

Letter to the Editor: In order to qualify for a kidney or heart transplant the prerequisite is disease of the organ that is life threatening and beyond hope of repair through treatment. The basic cause for the disease state plays little role in decisions to replace the heart or kidney. Moral questions do not apply in deciding who gets a donor organ. This is not the case when it comes to liver transplantation for those suffering from liver failure as a result of alcoholism.

A case in point was that of the infamous James Earl Ray, found guilty of assassinating Reverend Martin Luther King, Jr. He was allowed to die, while imprisoned, of liver failure resulting from cirrhosis without being given a chance at survival with a transplant. He may as well have been executed. He was not offered treatment that a non-criminal man or woman would have qualified for with a similar disease. This decision not to treat by transplantation is subject to debate, since there have been questions raised concerning, the reopening of the investigation concerning Ray's role in the murder and the possibility that he did not act alone but rather was a partner to a conspiracy. These questions were raised by the King family who felt that his denial of guilt had validity. Now it is too late.

When I asked the transplant surgeon at Yale about the alcoholic with liver failure, I was told that a person with a history of alcoholism generally must have a period of ongoing sobriety for at least six months before being able to get on the waiting list for a transplant. This, of course, means that alcoholics with severe liver damage who fail to respond to a period of abstinence and who are too physically ill to participate in and benefit from the standard treatment programs for alcoholism are effectively condemned to death. In a sense they are like James Earl Ray, condemned to death because of being who they are—alcohol dependent and therefore unworthy to receive the same level of care available to sober, law abiding citizens.

Since alcoholism is currently considered a disease—and there is increasing neurochemical and genetic information to substantiate that thesis—it would seem appropriate to reconsider the parameters of eligibility for organ transplant. It would seem logical to offer transplant in cases of emergency without demanding that a specific period of sobriety be a criterion for eligibility. It would be appropriate, perhaps, to contract formally and in writing with the individual in hepatic failure, who needs immediate liver transplant in order to survive, specifying that, upon recover from the surgical procedure, treatment for alcoholism must be undergone. In this way the question of unfair discrimination against the sick alcohol- dependent person would be avoided.

I would welcome comments from the readers of *Connecticut Medicine* regarding this issue.

Henry N. Blansfield, M.D.
Danbury

SUMMARY OF PROCEEDINGS
CSMS HOUSE OF DELEGATES—ANNUAL MEETING
RAMADA INN, MERIDEN—13 MAY 1998

Reports and Addresses

The House received reports, addresses and/or remarks from the incoming President and the retiring President, Secretary, Treasurer, the Chairman of the Council, Delegates to the AMA, Chairman of the Board of Directors of COMPAC, the CSMS Executive Director, CSMS/IPA, Connecticut Medical Insurance Company (CMIC), Standing Committees, Representatives and Advisors, and Delegates from the Maine Medical Association, Massachusetts Medical Society and the Medical Society of the state of New York. All of the reports and resolutions were published in the Handbook that was distributed to the delegates. The addresses of the Executive Director, Tim Norbeck, and the retiring President, Stanley J. Keating, Jr., M.D. appear at the conclusion of this summary. The inaugural address of the new President, Craig W. Czarsty, M.D., appears as the President's Page in this issue.

PRINCIPAL ACTIONS TAKEN
Election of Officers and others

The House voted to approve the published report of the Nominating Committee (the Council). Officers elected were:

President: Craig W. Czarsty, M.D., Oakville

President-Elect: Stephen R. Katz, M.D., Fairfield

Vice-President: Donald D. Timmerman, M.D., Portland

Secretary: Brian Van Linda, M.D., Avon

Treasurer: Roger S. Beck, M.D., Wethersfield

Speaker of the House of Delegates:
Howard J. Wetstone, M.D., Hartford

Vice-Speaker of the House of Delegates:
John P. Bigos, M.D., New London

Councilor-at-Large: Stanley J. Keating, Jr., M.D., Hartford

Delegates and Alternates to the American Medical Association:

Anthony P. Redmond, M.D., Greenwich (D)
1/1/98-12/31/99
Joseph C. Czarsty, M.D., Waterbury (A)
1/1/98-12/31/99
Jerome Bobruff, M.D., New London (D)
1/1/98-12/31/99
Sultan Ahamed, M.D., Norwich (A)
1/1/998-12/31/99
Francis J. Scarpa, M.D., Greenwich (D)
1/1/99-12/31/00
Neil H. Brooks, M.D., Rockville (A)
1/1/99-12/31/00
Joseph S. Sadowski, M.D., Hartford (D)
1/1/99-12/31/00
Dickerman Hollister, Jr., M.D., Greenwich (A)
1/1/99-12/31/00
Mehdi S. Eslami, M.D., Waterbury (D)
1/1/99-12/31/00
John B. Franklin, M.D., Hartford (A)
1/1/99-12/31/00

In approving the report of the Nominating Committee, it was also voted to disband the Committee on Data Study and the Committee on Statewide Medical Planning.

Following are the actions taken on the business that came before the House:

OLD BUSINESS

At the 1997 semi-annual meeting, the following resolutions were referred to the Council by the House of Delegates for implementation: The report of the Chair of the Council included the following information:

CREATION OF CSMS PATIENT MANAGEMENT CARE COMMITTEE

A committee has been appointed to be composed of eleven members, and Dr. Donald Timmerman has been named as Chair. The committee has been charged to carry out the functions outlined in the resolution which are:

- To act as a liaison between patients and the appeals committee created by a substitute House Bill 6883, as amended to expedite quality, access, and fairness.
- To engage the Department of Insurance and the Department of Public Health of Connecticut to work in concert with CSMS to assure physician input into implementation of House Bill. 6883.
- To receive, collect, and research information concerning problems within the managed-care industry.
- To report to the House of Delegates and Council and to the appeals committee when appropriate

LENGTHEN THE DURATION OF THE HOUSE OF DELEGATES

A survey was conducted among the county delegates and alternate delegates which included 15 questions. Out of 145 responses, 109 preferred the half-day session starting at 12:00 noon. The Council appointed the Chair of the Council, the president, and president-elect to discuss with the speaker and vice-speaker the other issues in the questionnaire and ways and means to attract more delegates to the meeting.

NEW BUSINESS

THE HOUSE VOTED TO OPPOSE THE FOLLOWING RESOLUTION ON THE BASIS OF IT BEING TOO VAGUE AND ALL ENCOMPASSING

RESOLUTION; Endorsement of Single-Payer Catastrophic Coverage

Resolved; That the Connecticut State Medical Society endorse single- payer catastrophic coverage for all American citizens.

THE HOUSE VOTED TO APPROVE THE FOLLOWING RESOLUTIONS

RESOLUTION; Medicare—Cures for Billing Code Complexity

Resolved; That the Connecticut State Medical Society propose abandoning the concept of levels of care as the method for reimbursing physicians for their Medicare services, and instead support the predetermined reimbursement for each service based on the type of service; (ie, office visits, consultations, and re-evaluations, hospital admissions and visits, emergency room visits, house calls, nursing home visits, etc). The reimbursement has to be fairly and carefully determined by all concerned parties, and allow for regional variations in cost of living, professional liability insurance, practice costs, etc. Therefore, the fees should simply be adjusted each year for inflation, and be it further

Resolved; That the Connecticut State Medical Society shall transmit to the American Medical Association for its adoption a copy of this resolution supporting the concept of reimbursing physicians for their services provided to Medicare patients based on the type of service instead of levels of care.

RESOLUTION: The Criminalization of Health Care Decision-making

Resolved, that legal counsel for the Connecticut State Medical Society shall conduct a review and analysis of the current state statutes and case law as these relate to defining criminal conduct and the potential for criminalizing health care decision-making; and be it further

Resolved, if necessary, the Connecticut State Medical Society shall seek corrective action in the state statutes properly defining criminal conduct and prohibiting the criminalization of health care decision-making and be it further

Resolved, if necessary that the Connecticut State Medical Society shall implement an appropriate action plan to educate opinion leaders, elected officials, and the media regarding the detrimental effects on health care resulting from the criminalization of health care decision-making.

RESOLUTION; Relief of Membership Dues for Retired Physicians not yet 65 Years of Age Who Provide Pro Bono Medical Care

Resolved, that the Connecticut State Medical Society shall amend its bylaws to allow for no dues for those physicians who fully retire but have not yet attained the age of 65 and provide at least 30 hours of pro bono medical care each year either locally or abroad. The affected physicians would be required to submit a statement annually to the Connecticut State Medical Society attesting that they have met this requirement for total dues reduction.

RESOLUTION; Prohibit Hospitals from Using Board Certification as a Single Criterion for Nonacceptance on their Medical Staffs

Resolved; that the Connecticut State Medical Society strongly recommends that hospital medical staffs not use board certification as a sole criterion for accepting or terminating physicians from their medical staffs.

The resolution on Opposition to the Evaluation and Management (E&M) Coding Guidelines was withdrawn.

AWARDS

American Medical Education and Research Foundation (AMA-ERF)

Dr. Keating presented the following awards:

University of Connecticut School of Medicine ... $8,142.03—Bruce Koeppen, M.D., Dean, Academic Affairs and Education, accepted the check.

Yale University School of Medicine ... $9,730.06—Myron Genel, M.D., Associate Dean of Government and Community Affairs, accepted the check.

Connecticut Science Fair Awards

Dr. Keating announced the following awards:

First Place—*Senior Division*—Christina Jagielski, Ninth Grader, Guilford High School

Project: "Does Stroop Effect Change as We Get Older?"

Second Place—*Senior Division*—Becky Gold and Jana Barkin, Eight Grader, Hillel Academy in Fairfield

Project: "Quantitative Analysis of Pesticides in Baby Food, Fresh *vs* Commercial"

First Place—*Junior Division*—Melissa Rothwax and Adina Muller, Eight Grader, Hillel Academy in Fairfield

Project: "Effect of Various Antibiotics and Ingested Liquids on Common Bacterial Growth"

Second Place—*Junior Division*—Michael Mola, Seventh Grader, All Saints Catholic School in Norwalk

Project: "A Germ is a Terrible Thing to Spread"

The first place winners received a plaque and a check. The second place winners received a plaque and a book.

Award to Retiring President

Dr. Joseph Sadowski, Chair of the Council, presented a Paul Revere silver bowl and past president's pin to Stanley J. Keating, Jr., M.D.

Inauguration of New President

Dr. Joseph C. Czarsty gave the Oath of Office to the new president, Dr. Craig W. Czarsty, (his son) and presented him with a gavel and a presidential medallion inscribed with his name and date.

PAST SERVICE AWARDS TO OFFICERS

Dr. Keating presented the following with silver bowls:

Roger S. Beck, M.D.,
Delegate to AMA, 1990-1997

Edward A. Kamens, M.D.,
Delegate to AMA, 1983-1997

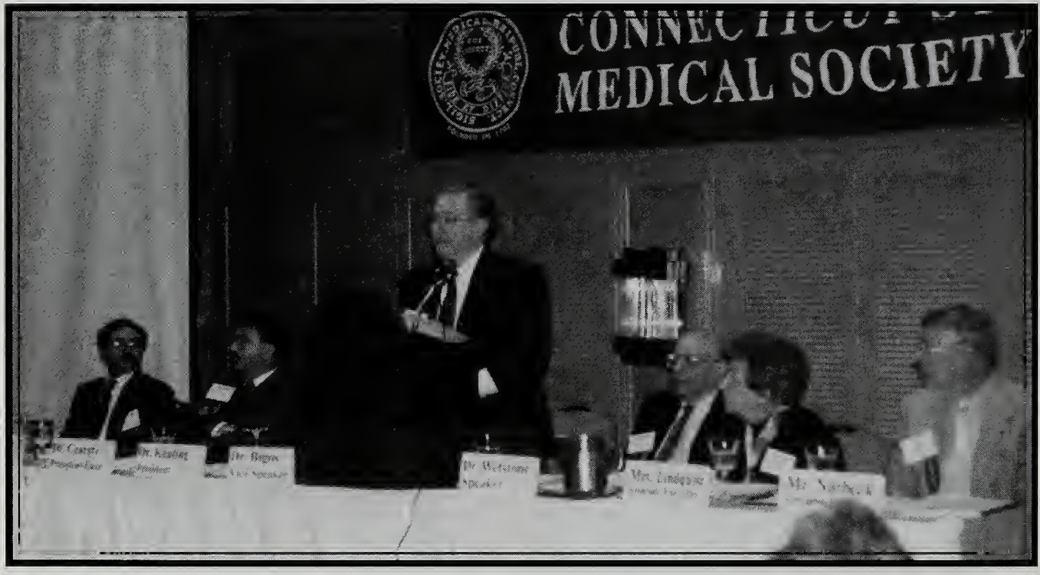
Stuart B. Mushlin, M.D.,
Vice-president, 1997-1998

Stanley J. Keating, Jr., M.D., president, presenting award to Edward A. Kamens, M.D., Fairfield, for his service as Delegate to AMA, 1983–1997.

Stanley J. Keating, Jr., M.D., president, presenting award to Stuart B. Mushlin, M.D., Stamford, for his service as vice president of CSMS, 1997–1998

Stanley J. Keating, Jr., M.D., president, presenting award to Roger S. Beck, M.D., Wethersfield, for his service as Delegate to AMA, 1990–1997.

Stanley J. Keating, Jr., M.D., center, presenting checks on behalf of the AMA Education and Research Foundation to Myron Genel, M.D., left, who accepted the check for Yale ($9,730.06) and Brucke Koeppen, M.D., who accepted the check for the University of Connecticut School of Medicine ($8,142.03).



Stanley J. Keating, Jr., M.D., giving his report as retiring president.

Joseph S. Sadowski, M.D., chair of the CSMS council, preenting a silver bowl and past president's pin to Stanley J. Keating, Jr., M.D.

Josph C. Czarsty, M.D., administering the oath of office of the president to his son, Craig W. Czarsty, M.D.,, Oackville. His wife Margaret, and mother Roberta are in the backgrond.

Howard W. Wetstone, M.D., Speaker of the House of Delegates, congratulating Dr. Czarsty.

Craig W. Czarsty, M.D., giving his inaugual address.

Craig W. Czarsty, M.D., newly elected president, with his wife Margaret, mother Roberta, father Joseph C. Czarsty, M.D., and daughter Beth.

Craig Czarsty, M.D., with his wife Margaret.

Science Fair Award Winners (from L-R) Michael Mola, Christina Jagielski, Melissa Rothwax, Adina Muller, Becky Gold, and Jana Barkin.

Address of the Executive Director

CSMS Annual Meeting—House of Delegates

13 May 1998

TIMOTHY B. NORBECK

BACK in the early 1940s, years before he became Harry Truman's vice president, Alben Barkley was shaking hands in a small Kentucky town and asking voters to return him to the U.S. Senate. Suddenly he saw a longtime acquaintance across the street. Barkley made a beeline towards him, but the fellow crossed the street in what seemed to be an effort to avoid him. The old-timer, Barkley was told by a bystander, was mad at him.

So the senator crossed over again and confronted his straying constituent. Barkley reminded him that when World War I ended, he helped get the man's son back home from Europe to help on the farm. "Yes," said the man, "you did that." "And didn't I get you a disaster loan when the Ohio River washed you out?" "Yes," said the man, "you did." "And didn't I help your daughter get a job?" Barkley continued. "Well, yes you did," his constituent answered. "Then why are you against me?" asked Barkley. "Well, said the old-timer, "you ain't done nothing for me lately."

Senator Alben Barkley was trying to keep his constituents satisfied back in the old days when most Americans held Washington in high esteem. Those days are over, of course, and voters today view our nation's capital with considerable cynicism. But this time it works to our advantage.

Generally Democrats, who oppose our efforts for tort reform, tend to be on our side in managed-care reform. Conversely, generally Republicans, who are our friends in tort reform, oppose us on managed-care reform.

All the polls clearly show that U.S. voters are worried about the availability, choice, and quality of medical care—and are looking to the Democrats to do something about it. Needless to say, during this important election year, Republicans are mindful of this attitude. One top GOP consultant confesses that voter anger has created a "political imperative" for the Republicans to address the problems of managed care. In just one of those polls, 91% of women and 88% of men questioned supported the patient's bill of rights. In a recent AFL-CIO survey of the American public, 85% of respondents were most concerned about HMO limitations on their choice of doctors.

Republicans in Washington are now talking about the need to give American workers more choice—in physicians and health plans. Their leadership is getting heat from business which opposes any new costs, red tape, or other restraints.

But the polls and voter anger will supercede those concerns. Republicans are even talking about addressing the uninsured problem. It bodes well for us in our efforts to secure meaningful managed-care reform.

Things are looking up for physicians as well on the tort reform front. As you may recall a few years ago, the U.S. House of Representatives passed substantial tort reform which included a $250,000 cap on pain and suffering. The Senate was unable to take similar action, however, because 60 votes were needed for cloture to prevent a filibuster, and the votes weren't there. If Republicans pick up an additional five seats in the Senate this year, they will have those 60 votes and could, if united, prevent a filibuster.

Members of this House of Delegates know how I dislike kidding lawyers, but I will make an exception since we were just talking about tort reform.

It seems that this lawyer, having passed on and left this world behind, found himself with the devil in a room completely filled, wall to wall, with clocks. The lawyer was fascinated with the vast collection and noticed that each clock moved at a different speed and was labeled with the name of a different occupation—dentist, teacher, salesman, and so on. He was also puzzled because the clock labeled "physician" hardly moved at all.

"I have two questions," said the lawyer to the devil. "First, why does each clock move at a different speed?"

The devil replied, "The clock hands turn at the rate at which members of that occupation tell a lie. What is your second question?"

"My second question is that I've looked around and I can't find the clock for lawyers. Why don't you have one for my profession?"

"Oh, we do," said the devil, "but it's down in the workshop. They're using it as a fan."

Despite some solid legislative successes, it is no secret that physicians are deeply upset today by the continuing and escalating efforts to depersonalize them along with the status of the noblest profession of them all. Physicians feel isolated, powerless, and even faceless.

Physician practices today remind me of an old Woody Allen saying: "Most of the time I don't have any fun. The rest of the time, I don't have any fun at all."

Perhaps Ogden Nash was thinking of managed care when he said: "Progress may have been all right once, but it went on too long."

The business of medicine, not the practice of medicine, seems to reign.

Managed care is one thing, the dark side of managed care is quite another. People are asking the $64,000 question: Is the system about managing the care of patients or about managing those who care for the patients? What other business succeeds by imposing austerity and restraint on others? What other business thrives in such proportion to its carrying out that austerity? What other business prospers so much by limiting choice?

And then there is the matter of HCFA's revised documentation guidelines for evaluation and management services—which presently will increase the threat of fraud and abuse prosecution. As Abe Lincoln said: "If all you have is a hammer, pretty soon everything around you starts looking like nail." As you probably know, physicians did receive a small reprieve when AMA prevailed on HCFA to approve a six-month postponement of the 1997 guidelines.

The good news is that there is somebody out there listening, somebody out there who cares, somebody out there doing something about it.

Survey after survey finds deep public mistrust of HMOs and a desire to choose one's own physician. The bottom line is that sick people are people who are forced to trust. And the politicians finally have come to realize that. Harvard University health policy professor Robert Blendon says that discontent with managed care will grow, particularly in California, where almost all consumers are enrolled in managed-care plans. He contends that Californians are unhappier than the rest of the country. People are more aware of what has happened in California, and the public and a growing number of legislators recognize that American medicine can ill afford the "Californication" of its health system.

As you know and as a result of our managed-care reform successes this past year, the legislature declared a moratorium on any further such reform until legislators have had the opportunity to assess its impact. After initial objections, we were successful in convincing legislative leaders that securing relief from delayed payments from HMOs did not constitute managed care reform in the pure sense of the term. It is unconscionable for managed-care organizations to withhold payment, enrich themselves in the process, and not have to worry about any penalties. What some have learned about rationing treatments to patients, they have applied to rationing payments to physicians and other caregivers. We won another magnificent victory—there will be prompt payment from managed-care organizations, or there will be penalties to pay. Fairness did prevail, and we thank all of you in this House who called or wrote their legislators and who urged colleagues to call.

Had we not achieved success with that strategy, we might have had to resort to a more drastic measure. Much like the story involving Father O'Malley who was saying his goodbyes to the parishioners as he did following every Sunday morning service. One of them, a young married woman named Mary Clancy, came up to him in tears. "What's bothering you so, my dear," he inquired. "Oh, Father, I have terrible news." "Well, what is it?" he asked. "My husband passed away last night," she sobbed. "Oh, Mary," said Father O'Malley, "that's just awful. Tell me, child, did he have any last requests?" "Well, yes he did, Father." "What did he ask, Mary?" "Father, his last request was: 'Please, Mary, put down the gun.'"

As for those treacherous and unfair HCFA E&M guidelines, I do believe that help is on the way. Our CSMS Medicare Committee has met and proposed alterations and changes to the AMA for transmission to HCFA. The AMA held a national meeting two weeks ago on this very subject in Chicago, and CSMS was there. Connecticut's Dr. Neil Brooks was also there as national president of the American Academy of Family Physicians. HCFA appears to agree that the implementation of the guidelines must be rewritten and the effective date be further postponed until 1999 when pilot studies and education will be completed. Medicare carriers are being instructed not to punish physicians for honest mistakes. CSMS efforts to bolster the AMA position definitely helped.

We keep hearing from most of the managed-care organizations that regulation is not needed—let the market forces determine what happens, they whine. But that is not a viable solution. As Joseph Nocera of *Fortune* magazine points out: "The imperative that *Wall Street* demands of hot growth companies—that profits increase by eye-popping amounts year after year—doesn't quite jibe with the business of delivering first-rate health care to the public."

Health Insurance Association of America president Bill Gradison and other industry leaders insist that if left alone, without regulation, the insurers would eventually set everything right. But a new study by Families USA makes you wonder. One finding: high-level executives at the nation's largest for-profit HMOs—those same people arguing that we can't afford a bill of patients' rights—enjoyed an average compensation of more than $6 million a piece in 1996. That may not say it all, and I don't want to sound cynical, but as *Newsweek* points out, it does say a lot about who counts most when the industry is left to look after itself.

The insurers need a little comeuppance. Like the story about the mother, accompanied by her small daughter, in New York City. The mother was trying to fetch a cab when her daughter noticed several wildly dressed women who were loitering on a nearby street corner. The mother finally hailed her cab and they both climbed in, at which point the daughter asked her mother, "Mommy, what are all those ladies waiting for on that corner?" To which the mother replied, "Those ladies are waiting for their husbands to come home from work."

The cabbie, upon hearing this exchange, turned to the mother and said, "Ahhhhhh, C'mon lady! Tell your daughter the truth! For crying out loud. They're hookers!"

A brief period of silence followed, and the daughter then asked, "Mommy, do the ladies have any children?"

The mother replied, "Of course, dear. Where do you think cab drivers come from?"

On my way to one of our 6:30 A.M. breakfast caucuses at the most recent AMA Convention in Dallas this past December, I came upon two bellhops earnestly engaged in a conversation—obviously at the end of their discussion. The one, clearly annoyed, said to the other: "Get a life. Find someone else to tell how bad everything is."

The bellhop who had complained about something should have heard about how the great Argentine golfer, Roberto DiVincenzo, handled some bad news. After picking up his winner's check at the tournament and posing for the obligatory smiles for the cameras, he went to the clubhouse and prepared to leave. Some time later, he walked alone to his car in the parking lot and was approached by a young woman. She congratulated him on his victory and then told him that her infant child was seriously ill and near death. She did not know how she could pay the doctor's bills and hospital expenses.

DeVincenzo was touched by her story, and he took out a pen and endorsed his winning check for payment to the woman. "Make some good days for the baby," he said as he pressed the check into her hand.

The next week he was having lunch in a country club when a Professional Golf Association official came to his table. "Some of the boys in the parking lot last week told me you met a young woman there after you won that tournament." DeVincenzo nodded. "Well," said the official, "I have news for you. She's a phony. She has no sick baby. She's not even married. She tricked you, my friend."

"You mean there is no baby who is dying?" said DeVincenzo. "That's right," said the official.

"That's the best news I've heard all year," replied DeVincenzo....

As Wisconsin health-care consultant Daniel Beckham put it: "There are two clear realities in the sea of complexity that is the health-care market: You can't provide medical care without doctors, and consumers value a relationship with a physician above any other in the delivery system. Physicians have much more power to influence their situation then they have yet realized. Their relationship with their patients represents the fundamental point of leverage in the health-care market place."

In closing, a columnist for the *Cincinnati Inquirer* made the following plea to physicians on National Public Radio two years ago this August. It's something to think about. "Isn't it about time" she said, "that you rescue medicine from the questionable mercies of business and politics? You were the smartest kids in the class so why are you letting everybody else tell you how to do your job? You people who became doctors were the brains, the bookworms, the merit scholars, the Eagle Scouts, the hall monitors. You were the ones whose homework the rest of us copied because you had the answers. You are the people with the magnificent arrogance to put your hands around a pulsing human heart. You are the voices that are bright enough to give us the bad news. Are you scared of a bunch of bean counters? Why have you allowed insurance companies and managed care to demand that young couples leave the car running when they enter the maternity ward. I beg you—get back in the game. When I am sick I'd still like to know there is a doctor in charge, not some MBA. I certainly don't want Ted Kennedy or Newt Gingrich to be taking my temperature."

Don't get too discouraged, you dedicated missionaries of medicine—despite the dark side of managed care, despite the eternal criticisms from those who don't even begin to understand your problems, and despite the infernal paper work and the constant hassles. You are making progress, but your unity and legislative and political involvement is essential to swing that pendulum back for your patients. Get back in the game!

We may not be exactly where we want to be, and we're not where we deserve to be, but we are not where we used to be. We have advanced the cause, and with your help and guidance, we will persevere—and we will prevail.

Never doubt for a moment that a small group of thoughtful and committed citizens can change the world. As anthropologist Margaret Mead said: "Indeed, it is the only thing that ever has."

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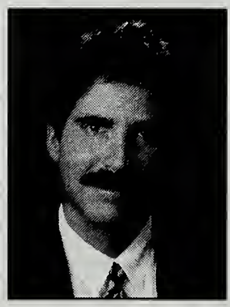

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CSMS Annual Meeting—House of Delegates

13 May 1998

STANLEY J. KEATING, M.D.

IT strikes me that there are two available options in formulating remarks for an address such as this. One is to reflect on the past year of my stewardship as president. Another is to attempt to articulate a vision of our future, its challenges and potential rewards, drawing upon my experiences of these past several years.

I am reminded of a scene from a movie of the 1980s, the plot of which centered around a proposed cross-country automobile race. In one scene, one of the protagonists approaches his racing car, a Lamborghini or similarly exotic machine, aviator glasses in place, leather helmet, leather jacket, silk scarf jauntily draped around his neck. As he settles into the cockpit, he surveys the interior, glances at the rear view mirror, and in a sweeping motion detaches the mirror from the wind screen and tosses it out the side window with the comment that, at this stage, anything behind him is totally irrelevant.

Nothing could be further from our truth. There is no question that the capabilities of our society in affecting public policy in matters of health care have become a steady and increasingly relevant influence in the business sector, in our institutional relationships, and in the political and public service sector. Relationships with the health department, the insurance department, and both houses of the legislature have been cordial and increasingly productive in matters of mutual concern. Increasingly the society is seen, as we would wish ourselves to be perceived, as advocates for our patients' interests and the public health.

Our accomplishments in forwarding our interests in the state legislature have been extremely gratifying. The Commiffee on Legislation, its chairman David Park, and our wonderful executive staff cannot be congratulated enough. A further reason for optimism is the evident willingness of individual physicians, as well as the component specialty societies, to engage with us as proponents of our mutual interests.

The existence of M.D. Advantage affords us an entree to the commercial sector heretofor unavailable to a significant sector of our constituency. We must have the ability to deal with all manner of corporate entities both purveyors and purchasers.

Costs related to the delivery of health care are legitimate concerns and demand our attention. Allowing our system to evolve to the point where the consumer is insulated from the cost of medical care by third-party payors has proven to be a recipe for disaster. Overpromised and underfunded, medical care is caught between expectations of our own, our patients, and the system's providers. One result has been a rather precipitous decrease in the percentage of workers covered by employer-funded medical insurance programs. The business community is increasingly interested in defined contribution plans and in some areas of the country, direct contracting.

There is an opportunity here for us if we are to regain and retain control of the delivery of medical care to our patient constituency. To control utilization and to articulate clearly outcome data is the heart and soul of the issue. It is obvious, at least to me, that current systems of network integration are inadequate. Information systems and access to capital are critical to achieving our goals. An adequately capitalized physician organization must be more competitive than any entity having to disperse funds to shareholders.

Let us consider that ultimately our goal should be a system of expanded choices of financing mechanisms. Allow the individual ownership of insurance policies with the periodic right of changing coverage. Allow employers to make defined contributions to the employee's plan choice. Redefine the existing tax credit system affecting this type of insurance.

Our market-based system should be strengthened to avoid a government-based system of price controls: limiting choice, stifling innovation, and leading to an overall decline in quality. Only physicians can manage care. Organizational structure is vitally important. We must have organizations of size, both in numbers and capitalization, in order to impact and control costs and quality of care.

M.D. Advantage is a step forward. CSMS-IPA has been in existence for a number of years now. Many of us are charter members and it is a wholly owned subsidiary of the Connecticut State Medical Society. In its relationships with its HMO partner it serves as an object lesson to all of us in the advantages and pitfalls of ventures of this type. We need always to remind ourselves that an IPA's primary responsibility is to the well being of its physician constituency, understanding that a symbiotic relationship in fact exists with the management partner.

What challenges await us beyond managed care in the near future?

A vitally important component of our organization, and indeed the medical profession, is the concept of collegiality. For generations our profession has prospered through a system of shared knowledge and experiences combined with a critical but always supportive and educational examination of each other's performance. This system has allowed us constantly to evolve diagnostic and therapeutic modalities, to share each others expertise. Until today American medicine clearly leads the world in our broadly based medical delivery system and research capability. That attention needs to be paid to the cost-efficient delivery of medical care is a given, but financial interests must not be allowed to disrupt the sharing of knowledge and techniques, the free utilization of medical resources that so typifies current medical practice. We owe it to ourselves to insure that the nonprofessional managers of managed care are not allowed to intrude on the quality of care so long nurtured by all of us.

A corollary concern is the increasing attention we must all give to the field of bioethics. Medicine as a profession, and all of us in this room, have long espoused a code of ethics and, upon receiving our degrees, swore an oath that in effect defined our relationships with each other and with our patients. It seems to me that for us to continue to thrive there must always be among us some fundamental agreement as to the proper utilization of this vastly expanding body of knowledge that constitutes the science of medicine.

Knowledge or truth is, I believe, inherently good; how that new knowledge is utilized is not. Grave dangers confront us if this new technology is misapplied. These issues should be of grave concern to us all. I applaud the inclusion of bioethics in the curriculum of an increasing number of our medical schools and the coincident development of academic departments of bioethics in these institutions. I hope we will all concern ourselves with ethical issues as they arise and the implications that this expanding technology may have for our society.

Finally I want to thank our chief executive, Tim Norbeck, and his entire staff for their unflagging support. I have found this to be a most rewarding year personally. It has been my privilege to represent you as your president. Thank you very much.

IN MEMORIAM

CONKLIN, CLIFFORD T,. Jr., University of Vermont College of Medicine, 1941. Dr. Conklin began his practice of medicine at Waterbury Hospital in 1946 and maintained a private practice in Thomaston. He was an assistant medical examiner for the state of Connecticut, served as the Thomaston health director, and from 1947 to 1960 was the towns' school physician. For 30 years, he was the physician for the Thomaston Fire Department. Dr. Conklin also practiced industrial medicine at local factories. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Conklin died 5 May 1998 at the age of 83.

GEER, E. THROOP, Temple University School of Medicine, 1944. Dr. Geer, a plastic surgeon, practiced in the Greenwich-Stamford area. He had been on the staff of the Greenwich, St. Joseph, and Stamford hospitals. For five years, he served as director of plastic surgery at Stamford Hospital. Former president of the New England Plastic and Reconstructive Surgery Society, Dr. Geer was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Geer died 12 April 1998 at the age of 79.

GOLD, LEONARD, Medizinische Fakultät der Universität Wien, Vienna, Austria, 1936. Dr. Gold maintained a private psychiatric practice in Stamford from the 1950s to the present. He was chairman of the department of psychiatry at Stamford Hospital from 1972 to 1985. He supervised residents and taught medical students at the New York Medical College and Stamford Hospital. Dr. Gold was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Gold died 22 April 1998 at the age of 88.

GOOD, ROBERT C., Columbia University College of Physicians and Surgeons, 1942. Dr. Good served the greater Waterbury and the Naugatuck Valley as an ophthalmologist for 40 years. He was on the staff of both Waterbury and St. Mary's hospitals, serving as president of the staff at St. Mary's. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Good died 24 March 1998 at the age of 82.

KAVOOKJIAN, HAIK P., Medical School, American University of Beirut, Beirut, Lebanon, 1950. Dr. Kavookjian opened a general practice in Darien in the 1950s, and later went on to specialize in urology. He was a member of the Fairfield County Medical Association where he served as a delegate to the Connecticut State Medical Society during the 1970s, and the Connecticut State Medical Society where he was active in the Section of Urology for 10 years and served on the Committee on Third Party Payments for 15 years. Dr. Kavookjian died 13 March 1998 at the age of 79.

KOH, JAMES, University of Pennsylvania School of Medicine, 1972. Dr. Koh was an orthopaedic surgeon in Milford for 19 years and was associated with Milford Hospital. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Koh died 29 April 1998 at the age of 52.

LEVINE, JULIAN, University of Vermont College of Medicine, 1950. Dr. Levine retired from family practice in Stamford in 1992. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society where he served on the Sports Medicine Committee in the early 1980s. Dr. Levine died 20 August 1997 at the age of 75.

MARTIN, JOHN G., Yale University School of Medicine, 1933. Dr. Martin began his family practice in West Hartford in 1933, retiring in 1983. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Martin died 3 May 1998 at the age of 90.

MILLER, HARRY B., Rush Medical College, 1932. Dr. Miller practiced dermatology in the Hartford area for almost 50 years. In addition to many regional and national dermatological societies, he was a member of the Hartford County Medical Assoiation, the Connecticut State Medical Society, and the American Medical Association. Dr. Miller died 26 April 1998 at the age of 94.

MLYNARSKI, JOSEPH A., Georgetown University School of Medicine, 1939. Dr. Mlynarski began his surgical practice in 1946 and served as senior surgeon at the New Britain General Hospital until his retirement in 1985 from active practice and from the New Britain Surgical Group that he founded. He served as Chief of Surgery at the New Britain General Hospital from 1963 to 1970. Dr. Mlynarski was assistant professor of surgery at the University of Connecticut School of Medicine. He was past president of the New Britain Medical Society; and a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Mlynarski died 31 March 1998 at the age of 84.

ROBERTSON, A. ROCKE IV, Temple University School of Medicine, 1942. Dr. Robertson, an obstetrician and gynecologist, practiced at Charlotte Hungerford Hospital for 34 years. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Robertson died 18 March 1998 at the age of 81.

SLATER, GERTRUDE, Medizinische Fakultät der Universität Wien, Vienna, Austria, 1937. Dr. Slater was a pediatrician and child psychiatrist. She was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Slater died 21 April 1998 at the age of 86.

WALKER, DONALD A., Tufts University School of Medicine, 1938. Dr. Walker retired from the practice of medicine in

1988. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Walker died 1 May 1998 at the age of 85.

WILSON, GEORGE L., Tufts University School of Medicine, 1947. Dr. Wilson practiced thoracic surgery at The Hospital of St. Raphael from 1956 until his retirement in 1992. He served on the board of trustees and was president of the medical staff at The Hospital of St. Raphael. Dr. Wilson was a clinical instructor of thoracic surgery at Yale University School of Medicine. He was a member of the New Haven County Medical Society, the Connecticut State Medical Society, and the American Medical Association. Dr. Wilson died 2 May 1998 at the age of 75.

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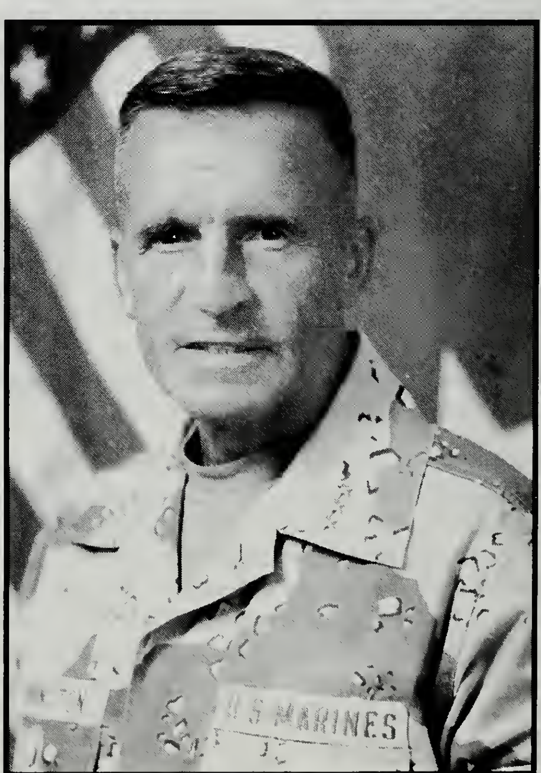

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***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

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VOLUME 62 JULY 1998 NUMBER 7

scientific:

Fadlallah Habr and Barry Wu 387 **Acute Transverse Myelitis in Systemic Lupus Erythematosus: A Case of Rapid Diagnosis and Complete Recovery**
Edward Christy and Stephen Atlas 391 **Hepatopulmonary Syndrome: A Case Report and Literature Update**
Latha Dulipsingh, Zahed Ikram, Carl D. Malchoff, and Kamal C. Shoukri 395 **A Cluster of Cases of Subacute and Silent Thyroiditis in the Greater Hartford Area**
Epitomes of Progress
Donald I. Feinstein 399 **Important Advances in Clinical Medicine—Internal Medicine**
Drug Information Update: Hartford Hospital
Alisha Dunn 413 **Sildenafil: A New Therapy for Erectile Dysfunction**
Morbidity and Mortality Weekly Report
417 **Assessing Adolescent Pregnancy—Maine, 1980–1996**
The Medical Letter
421 **A New Rabies Vaccine**

special articles:

Jack J. Falsone, Khalid Moidu, Catherine A. Sheehan, Karen Gottlieb, Laura Galusha, and Sreedhar Nair 423 **Is Telemedicine Justifiable?**

commentary:

Stephen R. Katz 429 **COURAGE—An Epistle to a Colleague**

departments:

Fifty Years Ago
433 **Medical Care and the Cost of Living**
434 ***Editorial:* A Corporate Society**
Max L. Berlowe, 434 **Vagitus Uterinus**
The President's Page
Craig W. Czarty 435 **What Is Your Excuse?**
Reflections on Medicine
Robert U. Massey 437 **A Sustainable Medicine**
Medical News Capsules
Timothy B. Norbeck 439 **This Month's Reading in Review**
Letters to the Editor
Edward J. Volpintesta 441 **Quality-of-Life and End-of-Life Decisions**
Victor A. Altshul 441 **In Defense of Linguistic Correctness**
James R. Merikangas 422 **Shortfall of Physicians?**
John A. Kirchner 422 **Literary Gaffes**

general:

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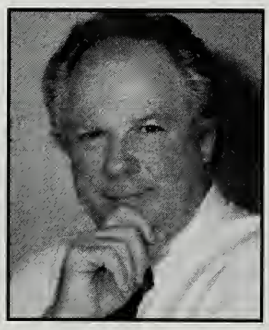

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Acute Transverse Myelitis in Systemic Lupus Erythematosus: A Case of Rapid Diagnosis and Complete Recovery

FADLALLAH HABR, M.D. AND BARRY WU, M.D.

ABSTRACT—Acute transverse myelitis is a rare and serious complication of systemic lupus erythematosus. Delay in diagnosis and treatment is associated with significant morbidity and mortality. Earlier diagnosis is facilitated by magnetic resonance imaging. Treatment of systemic lupus erythematosus-related acute transverse myelitis remains controversial. The use of steroids alone may result in incomplete recovery.

We report a patient who was promptly diagnosed with systemic lupus erythematosus-related acute transverse myelitis by magnetic resonance imaging. The patient had complete resolution of her symptoms following aggressive treatment with steroids and cyclophosphamide. Review of published treatment of systemic lupus erythematosus-related acute transverse myelitis suggests aggressive therapy with steroids and cyclophosphamide may provide the best outcome.

Introduction

ACUTE transverse myelitis (ATM) is a known complication of systemic lupus erythematosus (SLE).[1,2] It may be the initial manifestation of SLE, but most often occurs late in the course of the disease.[1,4] Patients present with lower extremity weakness, paresthesia, back pain, abdominal pain, and bladder and bowel dysfunction.[2,4-6] Physicians previously relied on cerebrospinal fluid (CSF) findings and myelography to diagnose ATM in SLE. The advent of magnetic resonance imaging (MRI) has facilitated earlier diagnosis and is less invasive.[4] Prompt diagnosis is important because untreated ATM may be fatal. We reviewed the published modalities for the treatment of ATM in SLE using intravenous steroids and pulse cyclophosphamide, and present a patient who responded to aggressive therapy.

Case

A 41-year-old woman presented in October 1994 with lower extremity weakness associated with bladder and bowel dysfunction. She was diagnosed with SLE in 1986 when she presented with fever, arthritis, pleural effusion, proteinuria, and tested positive for antinuclear antibody. A renal biopsy in 1987 revealed active lupus nephritis. The patient was treated with cyclophosphamide and prednisone and subsequently required long-term hemodialysis. Two days before admission, the patient was started on prednisone and azathioprine for biopsy-confirmed lupus pneumonitis. The next day she was unable to walk and complained of urinary retention and bowel incontinence. Neurological examination revealed 2/5 lower extremity strength, 3+ reflexes, bilateral Babinski responses, and decreased sphincter tone.

Laboratory data included an antinuclear antibody titer 1:640, anti ds DNA 220 U/mL (nL<3.6), anticardiolipin antibodies <10, CPK 189 U/L, and negative Lyme serology. Lumbar puncture showed white blood cells, 19, erythrocytes,10/μL,[3] protein 74 mg/dL, glucose 47 mg/dL, and bacterial antigens negative. MRI of the spine revealed abnormal signaling from T-3 level to the conus medullaris, with a centrally decreased signal on T-1 and increased signal on T-2 weighted images without en-

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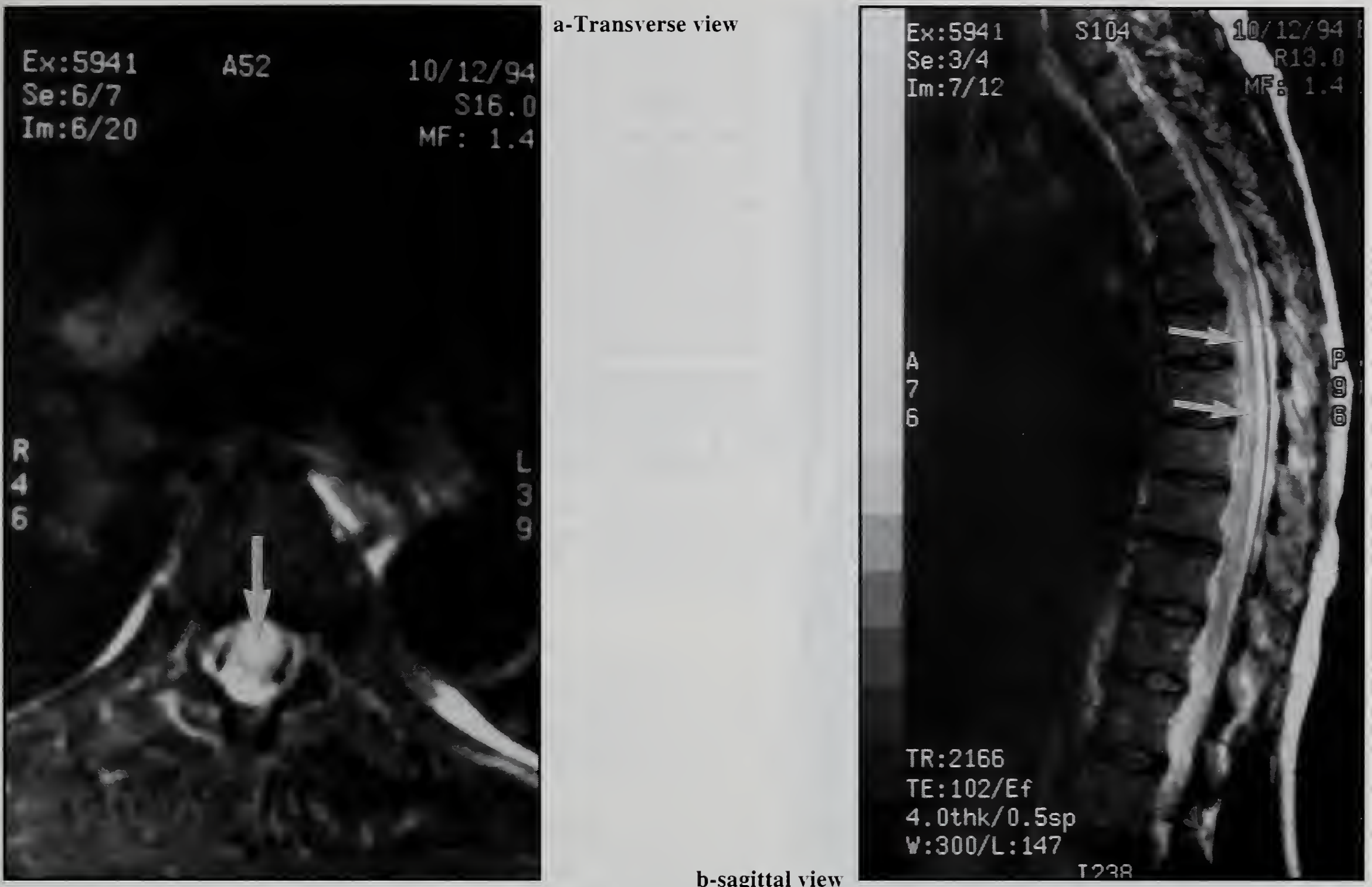
Table 1.—Summary of the presenting symptoms in SLE-related ATM in 11 subjects; laboratory and MRI findings, treatment regimens, and response.

Reference	Age, sex	Duration of SLE before onset of ATM	Presenting symptoms of ATM	APL antibodies	CSF	MRI	Treatment	Response to treatment
4	18 F	6 years	Flaccid paralysis of LE, back pain, urinary retention	(+)	P 200 mg/dL G 24 mg/dL	Widening of cervical cord, increase signal on T-2	Mpd x 3 days Cy monthly x 6	Normal strength after 3 months; partial bladder and bowel control
5	38 F	9 years	Back pain, weakness and numbness of LE, urinary and bowel retention	(–)	P 54 mg/dL G normal	Abnormal signal T-7–T-8	Mpd 1g/d x 3 followed by Mpd 1 mg/kg/day and Cy 100 mg/day	Death from sepsis after 6 months
5	22 M	5 years	LLE paresis, SL:T-6–T-7	(–)	P 124 mg/lL	Abnormal signal T-3–T-5	Mpd 1g/day x 3 Cy 20 mg/kg/day Ig 0.4 mg/kg/day and plasmapheresis	Spastic paraplegia after 12 months
2	31 M	8 years	Back pain, paraplegia, loss of bladder control	NR	P 142 mg/dL G 60 mg/dL	NR	Mpd 1 g/day x 3 Pdn 60 mg/day	Able to walk
6	NR	180 days	Paraparesis, neurogenic bladder SL:T-11		NR	NR	Mpd 3 g Cy 1.7 g then Cy 1.7 g/mo x 10 and Pdn 15 mg/day	Able to walk, neurogenic bladder
6	NR	60 days	Quadriplegia, loss of sphincter control, SL:C-4		Normal	NR	Mpd 6 g then Cy 1.34 g/mo x 3 Pdn 20 mg/day	Able to walk, total sphincter control
6	NR	60 days	Quadriplegia, loss of sphincter control, SL:T-7		Normal	NR	Cy 1.8g then Cy 1.8 g/mo x 12 Pdn 60 mg/day	Confined to wheelchair, partial sphincter control
6	NR	120 days	Paraplegia, neurogenic bladder, SL:T-5		Normal	NR	Mpd 3 g then Pdn 45 mg/day	Able to walk, neurogenic bladder
6	NR	90 days	Paraparesis SL:L-2		NR	NR	Mpd 3 g then Pdn 60 mg/day	Full recovery
6	NR	90 days	Paraplegia, loss of sphincter control, SL:T-5		NR	NR	Mpd 4.5 g Cy 1.5 g then, Pdn 60 mg/day	Death
6	NR	6 years	Paraplegia, loss of sphincter control, SL:T-5		Normal	NR	Mpd 3 g then Pdn 60 mg/day	Able to walk, adequate sphincter control

LE: lower extremity, SL: sensory level, APL: antiphospholipid, P: protein, G: glucose, Mpd: methylprednisolone, Pdn: prednisone, Cy: cyclophosphamide, Ig: immunoglobulin, NR: not reported



a-Transverse view

b-sagittal view

Figure 1.—Admission MRI showing increased signal on T-2 weighted images (arrows) consistent with inflammation within the spinal cord.

hancement. There was also widening of the spinal cord at the T-4 level (Fig. 1). These findings were consistent with transverse myelitis. The patient was treated with intravenous methylprednisolone 1 g daily for three days. Her neurological function improved initially but later deteriorated as the steroids were reduced. Intravenous pulse cyclophosphamide was given on the sixth day of hospitalization in addition to oral prednisone. She began ambulating without assistance, and regained her bowel function by discharge six weeks later. A follow-up MRI showed resolution of the previous abnormalities (Fig. 2).

Discussion

Central nervous system manifestations of SLE occur in approximately 60% of patients and rank second only to renal complications as the leading cause of death.[1] The neurological manifestations include seizures,[3] cranial nerve disorders, hemiparesis, chorea, tremors, and peripheral neuropathy.[1,3] ATM is a rare complication of SLE, occurring in only 1% of the patients.[10]

The histological findings of ATM in SLE are variable. Examination of the spinal cord of 12 patients with SLE-related ATM showed vascular changes in 11 patients.[1] The most common vascular lesions were perivascular round-cell infiltration, connective tissue proliferation, and thrombotic occlusion of the small arteries and arterioles, as well as microhemorrhages with perivascular gliosis in the cord parenchyma.[1] The pathogenesis of this disease may be an immune complex-mediated vasculitis resulting in infarctions or hemorrhages, antineuronal antibodies, or secondarily to a hypercoagulable state from antiphospholipid antibodies.[7] An association between anticardiolipin antibodies and SLE-related ATM has been reported.[10] Some have suggested these antibodies be tested in all patients with transverse myelitis.[10] Anticardiolipin antibodies, however, may not be present in all patients and were not found in our patient.

The diagnosing of SLE-related ATM had previously relied on CSF findings and myelography. CSF findings are not specific. Most patients have decreased CSF glucose,[1] increased CSF protein, and pleocytosis.[6] Myelography is invasive and less sensitive and specific in defining spinal cord pathology than MRI. MRI has aided in making earlier diagnoses. MRI findings of SLE-related ATM include decreased signal on T-1 weighted images and increased signal on T-2 weighted images with widening of the involved cord.

Definitive management of SLE-related ATM remains controversial (Table 1). Treatment with steroids alone often results in an incomplete recovery. Among 26 pa-

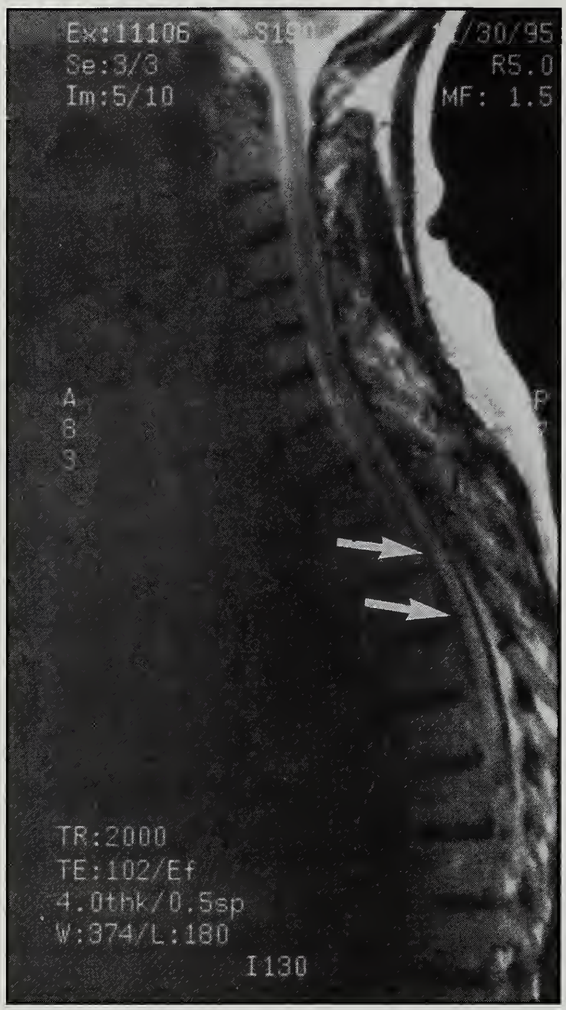


Figure 2.—Follow-up MRI one year later showing normal signal on T-2 weighted image

tients treated with prednisone or dexamethasone in one series, death occurred in 13 (50%), permanent neurologic deficit in nine (35%), and only four (15%) had nearly complete recovery.[1] Zerbini et al treated one patient with methylprednisolone 1 g daily for three days, followed by prednisone 60 mg per day and reported total recovery.[2] A more favorable response has been noted with the use of steroids and pulse intravenous cyclophosphamide.[4-6] Barille and Lavalle reported seven patients, six of them were treated with methylprednisolone 1 g for three days within the first four days. One had partial response to methylprednisolone and total recovery after addition of IV cyclophosphamide two months later. One patient failed to respond completely to only IV cyclophosphamide. Two were treated with methylprednisolone alone and had a satisfactory response. The last three patients received IV cyclophosphamide in addition to the methylprednisolone. Two had a satisfactory response and one died from a pulmonary embolus.[6] Our patient had a complete response to early treatment with steroids and cyclophosphamide.

Response to treatment of ATM in SLE has been variable. Early diagnosis and aggressive treatment with high-dose steroids combined with intravenous cyclophosphamide may result in an excellent outcome.

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Hepatopulmonary Syndrome: A Case Report and Literature Update

EDWARD CHRISTY, M.D. AND STEPHEN ATLAS, M.D.

HEPATOPULMONARY syndrome (HPS) is the association of hypoxemia with hepatic dysfunction and pulmonary vascular dilatation in the absence of parenchymal or pleural lung disease.[1,2]

HPS was first described in 1977 by Kennedy and Knudson,[3] and has received attention recently because of potential hypoxic complications associated with liver transplantation.[4]

HPS characteristically presents with orthodeoxia, defined as arterial deoxygenation accentuated in the upright position[5] and platypnea, defined as dyspnea induced by upright position and relived by recumbency.[6] Indeed, arterial oxygenation abnormalities are common in patients with hepatic disease; studies have reported that 45% to 69% of liver transplant candidates have abnormal arterial oxygenation.[53,54]

Case Report

A 39-year-old obese male multisubstance abuser was admitted with tibia and fibula fractures following a fall. He described having had shortness of breath on standing and exertion during the past year, with relief on lying down. There was no past history of cardiac or pulmonary disease. He denied jaundice, viral hepatitis, or a family history of liver disease.

The physical examination revealed: clubbing, hepatsplenomegaly, and an apical systolic flow murmur with a normal S1 and S2. There was no evidence of ascitis, spider nevi, or cardiac failure. The lungs were clear to auscultation.

Liver function tests included: alkaline phosphatase, 258 U/L (39-117); SGOT 122 U/L (0-37); SGPT 52 U/L (0-40); bilirubin 2.0 mg/dL (<1). Hemoglobin was 12.5 g/dL. Pulmonary function tests including forced expiratory volume in one second, forced vital capacity, and total lung capacity were within the normal range except for single-breath carbon monoxide diffusing capacity (DLCO) of 17.4 mL/min/mmHg (54% of predicted). Chest film revealed cardiomegaly with a mild increase in interstitial markings.

Abdominal ultrasound demonstrated parenchymal liver disease with recanalization of the umbilical vein, consistent with portal hypertension. Ventilation-perfusion lung scan and ultrasound of the lower extremities were unremarkable. Spiral computed tomography of the thorax failed to reveal pulmonary arteriovenous malformations, pulmonary emboli, or other parenchymal lesions including emphysema.

Technetium 99m-labeled macroaggregated albumin scan showed evidence of uptake in the brain, kidney, and the thyroid, consistent with right-to-left shunting (Fig. 1). A contrast echocardiogram showed left ventricular hypertrophy and delayed echogenicity in the left ventricle after the passage of bubbles through the right ventricle, consistence with pulmonary right-to-left shunting.

Discussion

The diagnosis of hepatopulmonary syndrome is suggested by the combination of orthodeoxia and platypnea. Confirmation is based on the following criteria: 1) abnormal liver function based on serum chemistry and ultrasound examinations; 2) the presence of intrapulmonary vascular dilatation confirmed by one of three imaging modalities: contrast echocardiography (bubble study),

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Table 1.—Arterial Blood Gas Analysis

	pH	Pco$_2$(mmHg)	Po$_2$(mmHg)	Pco$_3$(mEq/L)
Standing: Room air	7.48	33	56	24
Supine: 100% Fio$_2$	7.40	41	195	26
Standing: 100% Fio$_2$	7.43	36	110	24

99m-TC macroaggregated albumin lung scanning, or pulmonary angiography.

In a normal bubble study, the bubbles produce transient opacification or echogenicity in the right ventricle after the peripheral injection. These bubbles then pass into the pulmonary circulation where they are trapped in the capillary bed and do not appear in the left ventricle. Studies performed on patients with HPS have showed delayed opacification in the left atrium approximately three to six ventricular contractions after leaving the right ventricle.[8,9] This is due to dilated pulmonary vessels at the pericapillary level; ie, pulmonary shunting. In patients with cardiac septal defect, bubble studies would reveal immediate opacification in the left side of the heart.

99m-TC labeled macroaggregated albumin scanning is another method of detecting intrapulmonary vascular dilatations.[1,10–12] Macroaggregates exceeding 20 microns in diameter should be trapped in the normal pulmonary capillary bed, where capillaries are 8-15 microns in diameter. Normally 3% to 6% of macroaggregates may escape through the pulmonary vasculature but in HPS up to 71% shunting has been documented.[11]

Pulmonary angiography in many patients with HPS has demonstrated vascular abnormalities that appear predominantly in the middle to lower lung fields. The angiogram results may range from normal to diffuse, small "spider-like" branches.[58] Patients may experience worsening dyspnea when moving from supine to standing position as gravitational effects result in increased blood flow to the dilated vascular beds in the lung fields. The dilated capillaries are less efficient for oxygen diffusion, resulting in drop in Pao$_2$. This defines the phenomenon of orthodeoxia.

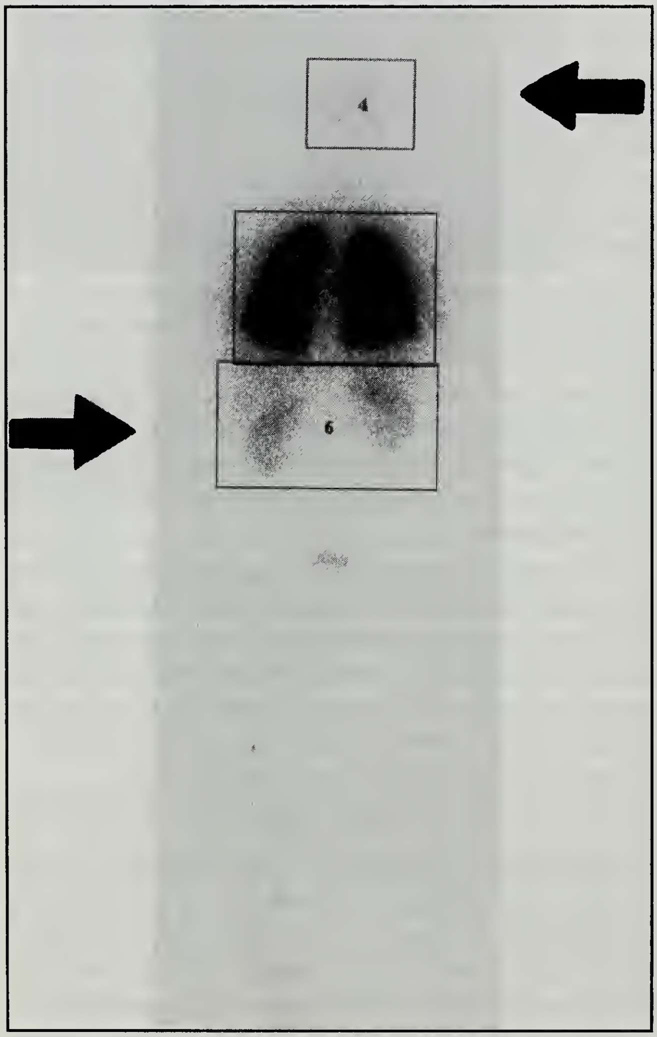

Figure 1.—Perfusion lung scanning with Tc-99m—abnormal uptake in brain, kidneys, and thyroid.

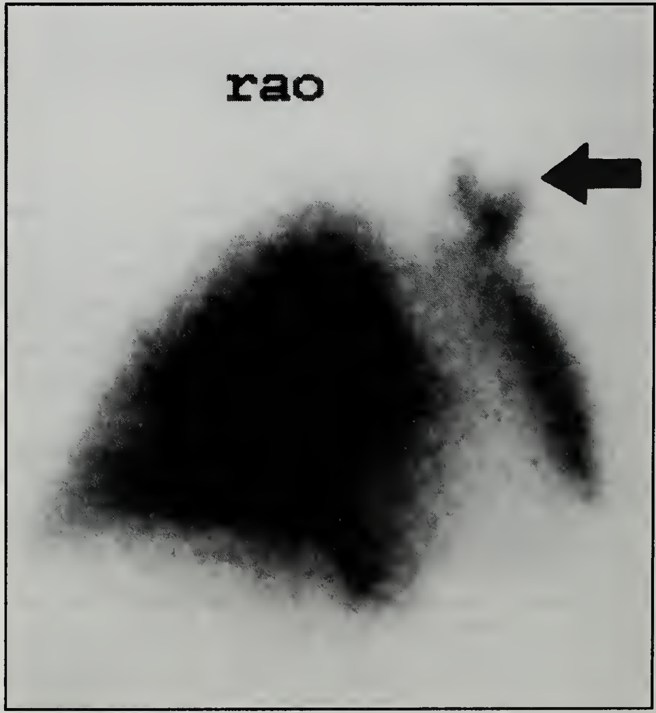

Figure 2.—Ventilation-perfusion scan—abnormal uptake of Tc-99m in the thyroid

Chest radiography of the patients with HPS characteristically shows increased interstitial and pulmonary vascular markings.[1,14–15] The pulmonary function studies reveal normal lung volumes and reduced single breath carbon monoxide diffusing capacity.

Our patient experienced platypnea and orthodeoxia. His liver function tests, hepatic ultrasound, bubble study, 99m-TC macroaggregated albumin lung scan (Fig. 2), and pulmonary function tests were all consistent with HPS.

The etiology of this syndrome remains unclear. One of several mechanisms that have been postulated is the failure of the damaged liver to clear circulating humoral mediators that are responsible for the pulmonary vasodilatation. The suspected mediators include prostacyclin, prostaglandin E1, prostaglandin I1,[12,16–17] nitric oxide,[20,21] vasoactive intestinal peptide,[22–24] glucagon,[25,26] calcitonin,[4] substance- P,[28] and endothelium- derived relaxing factor.[19,29] Nitric oxide's role as a vasodilator has been demonstrated to act by impairing vascular responsiveness to angiotensin II.[34]

Another postulated mechanism for HPS is the inhibition or metabolism of vasoconstrictors such as endothelin,[30] atrial natriuretic factor,[31,32] serotonin,[33] and tyrosine[1] which leads to unopposed pulmonary vasodilatation.

Treatment Considerations

Therapeutic approaches to HPS have included such treatments as indomethacin and other prostaglandin inhibitors,[35,36] estrogen blockers,[37] almitrine bismesylate,[38] octreotide,[39,40] garlic (Allium sativum),[41] sympathomimetics, β-adrenergic blockers,[42] cyclophosphamide,[43] prednisone,[43] plasma exchange,[4,44] and mechanical spring-coil embolization of pulmonary vascular dilatations.[52] Therapy for the HPS has been generally ineffective. The most successful of these therapies to date have demonstrated only minimal improvement in oxygenation and shunting.

Liver transplantation is the only promising modality available at this time.[4,7,13,46–48] The Cleveland Clinic series[45] revealed marked improvement in intrapulmonary shunting and improved oxygenation after liver transplantation. Anecdotal reports have described post-transplant hypoxemia as a complication in the recovery period.[4,49,50]

Conclusion

The natural history of the HPS is not well described because of a lack of prospective data. In one series, substantial deterioration in PAO_2 could be documented over 48 months in the setting of clinically stable hepatic function.[40] Spontaneous resolution or improvement of hypoxemia associated with HPS has been reported.[18,51] Despite limited understanding of the pathophysiology and natural history of the HPS, interventional radiology and liver transplantation may offer dramatic improvement in selected patients.[7,51] The mechanism of reversal, time to resolution, and predictors for reversal of hypoxemia remain undefined.

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A Cluster of Cases of Subacute and Silent Thyroiditis in the Northern Connecticut, Greater Hartford Area

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Introduction

SUBACUTE and silent thyroiditis are conditions that often are not recognized by physicians in Connecticut. In a random poll of endocrinologists in 1983, silent thyroiditis was shown to be a rare diagnosis on the east and west coasts of the United States and in Europe and Argentina but common around the Great Lakes in the United States and Canada.[12] Subacute thyroiditis is more common than silent thyroiditis, but accurate data on relative frequency are not available. Patients with subacute thyroiditis usually have an enlarged painful thyroid gland and serum thyroid hormone levels are generally elevated in the early stage of the disease, resulting in clinical hyperthyroidism. This disorder is thought to be initiated by a viral infection.

Silent thyroiditis on the other hand is painless but follows a similar clinical course and occurs frequently during the post-partum period. Human leukocyte antigen typing shows an increased frequency of D-related antigens, and thyroid antibodies are frequently positive, suggesting an autoimmune basis for the disorder.

We describe five cases of subacute and silent thyroiditis seen within a six-month period, all of them presenting in the winter and spring.

Abbreviations Used in Text

TSH = Thyroid Stimulating Hormone
T4 = Thyroxine
T3 = Triidothyronine
FT4 = Free Thyroxine

Case Reports

Case 1.—A 33-year-old woman had been under the care of neurologists for five years for progressive bulbar palsy. Over a four-month period, she described increasing cardiac palpitations, difficulty sleeping, intolerance to heat, frequency of bowel movements, and weight gain. The physical examination revealed tachycardia, a slightly enlarged thyroid gland that was tender on palpation, brisk deep tendon reflexes, and moist palms. Results of thyroid function tests done at that time were as follows: Thyroid stimulating hormone (TSH), <0.1 μU/mL (normal range 0.3–0.5 μU/mL); thyroxine (T4), 18.3 μg/dL (5.0–10.5); free thyroxine index (FTI), 21.5 (6.3–12.4); triiodothyronine (T3), 286 ng/dL (59–174). Iodine 131 uptake done 10 days later showed a 24-hour uptake of 0.4%. The hyperthyroidism was not treated in view of the mildness of her symptoms. Five weeks later her symptoms remained unchanged. She had gained more weight. Her thyroid gland remained mildly tender. Results of thyroid function tests done at that time: TSH, 17.3 μU/mL; T4, 4.1 μg/dL; FTI, 4.4; T3, 72 ng/dL. She was given a prescription for 50 μg of L-thyroxine orally once a day.

Case 2.—A 52-year-old man with a history of coronary artery disease was being evaluated for elevated LDL cholesterol and triglycerides. He stated that he had lost 19 pounds over the previous two months. During that period of time, he also had occasional cardiac palpitations, heat intolerance, and pain in the front of his neck. On examination his pulse rate was rapid and he had systolic hypertension. There was a fine tremor of the extended hands, and deep tendon reflexes were brisk. The thyroid gland was firm, nontender, and one and one-half times normal size. Results of thyroid function tests were as follows: TSH, <0.1 μU/mL; T4, 18.8 μg/dL; FTI, 26.1;

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T3, 328 ng/dL. Iodine 131 uptake was 0.9% at 24 hours. Thyroglobulin was 298 ng/mL (2.3–52.5), antithyroglobulin antibody and antinuclear antibody were both negative. Erythrocyte sedimentation rate (ESR) was 131 mm/hr (0–20). He was treated with metoprolol with improvement in symptoms. His repeat thyroid function tests four weeks later were: TSH, 2.1 μU/mL; T4, 4.8 μg/dLl; T3, <50 ng/dL; FTI, 6.4; ESR, 22 mm/hr.

Case 3.—A 48-year-old white female had had a cough and a sore throat for 10 days. Six weeks later, she began complaining of a dry cough, dry skin, lethargy, puffy eyes, feeling cold all the time, flatulence, constipation, and a prolonged heavy menstrual period. Her pulse rate was rapid and the relaxation phase of her deep tendon reflexes was delayed. The thyroid gland was about three-times normal, firm to palpation, and nontender. T4 was <0.5 μg/dL; TSH, 108 μU/mL; and ESR was 78 mm/hr. Iodine 123 uptake was 1.4% at 24 hours. She was given 75 micrograms of L-thyroxine once a day. TSH tests are repeated with the expectation that she will soon become euthyroid.

Case 4.—A 31-year-old white female had had amenorrhea for seven months; she had been taking birth control pills. She had no symptoms suggesting either hypothyroidism or hyperthyroidism. On examination, she was found to have enlargement of the lower part of the right lobe of the thyroid and a mild tremor of her outstretched hands. TSH was <0.1 μU/mL; free T4, 1.5 ng/dL (0.8-1.8); T3, 185 ng/mL. Iodine 123 uptake at 24 hours was 6.9%, with relatively increased trapping in a large area occupying the mid zone of the right thyroid lobe. Four weeks later, no enlargement of the thyroid was felt. Thyroid function test results were as follows: T4, 6.0 μg/dL; T3, 87 ng/mL; FTI, 7.6; TSH, 3.8 μU/mL. Four months later the patient was found to be clinically and chemically euthyroid.

Case 5.—A 22-year-old white male had a four-month history of anxiety, headaches, sweating, heart palpitations, and a 30 lb weight loss. He had systolic and diastolic hypertension and a mild sinus tachycardia even though he was on propranolol. The thyroid gland was about twice normal size, with an irregular surface. He had brisk deep tendon reflexes. Thyroid function test results: TSH, <0.1 μU/mL; T4, 10.1 μg/dL; FTI, 16.1; T3, 132 ng/mL. Iodine 131 uptake at 24 hours was 5%. He remained clinically and biochemically hyperthyroid for the next three months, with undetectable TSH and elevated thyroid hormone levels. Two months later his TSH was 1.8 μU/mL and the FTI was 9.4. His thyroid gland at this time was only slightly enlarged. He had not regained any weight, but a recent renal biopsy had revealed renal lupus, and he had been taking prednisone 20 mg for two weeks.

Discussion

Silent thyroiditis is an illness characterized by lymphocytic infiltration of the thyroid gland with transient hyperthyroidism followed by transient hypothyroidism. It is generally painless, with few or no systemic features. Although most patients have a partial or complete remission, follow-up studies ranging between one to 10 years have shown the persistence or later development of thyroid autoantibodies, goiter, or permanent hypothyroidism in a large proportion of these patients.[1,2] There is an association with other autoimmune thyroid disease including Graves' disease or connective tissue diseases such as systemic lupus erythematosus.[7] There is an increased frequency of HLA-DR3 in patients with silent thyroiditis, and HLA-DR3 and HLA-DR5 in patients with postpartum thyroiditis, which is a variant of silent thyroiditis.[2,8] The initiating event in silent thyroiditis is unknown. Seasonal clustering of cases and occurrence among close associates within a short period of time has been described, raising the possibility of an infectious etiology. However, researchers have been unable to identify an infectious agent or consistently demonstrate a rise in viral antibody titer.[1] Thyroid tissue, obtained during the hyperthyroid phase of silent thyroiditis, shows prominent focal or diffuse lymphocytic infiltration; however, tissue obtained during the hypothyroid or early recovery phase shows mild lymphocytic thyroiditis and regenerating thyroid follicles that contain little colloid.[4,9]

In contrast, patients with subacute thyroiditis usually have neck pain, thyroid tenderness, and systemic symptoms of inflammatory illness with or without symptoms of hyperthyroidism.[2,3] Often, there is a history of an upper respiratory tract infection within days or weeks preceding the onset of subacute thyroiditis. Elevation of the erythrocyte sedimentation rate and transient elevation in liver enzymes may occur during the illness. There may be a transient increase in thyroid autoantibodies and thyroid stimulating antibodies which gradually decreases over months following recovery.[1,10] Permanent hypothyroidism in the long term is not an usual occurrence. There have been case reports describing the occurrence of Graves' disease following subacute thyroiditis.[5,6] There is a strong association between subacute thyroiditis and HLA-B35.[2] Antibodies to a variety of viruses (eg, mumps, measles, influenza, infectious mononucleosis, Coxsackie virus, and adenovirus) have been shown to be elevated during the illness, but no viral inclusion bodies have been seen in thyroid tissue.[3] Epidemics of subacute thyroiditis as well as a seasonal occurrence, the highest corresponding with those of the summer enterovirus infection, have been described.[1] Thyroid tissue on biopsy shows lymphocytic infiltration, follicular cell destruction, and giant-cell formation.

The clinical course of both illnesses is similar. In patients with subacute thyroiditis symptoms usually last eight to 16 weeks, although they may last up to a year. In patients with clinical manifestations of hyperthyroidism, the signs and symptoms usually last four to 10 weeks. As the acute phase of the disease progresses, the colloid stores are depleted and patients become euthyroid even though symptomatic thyroid inflammation may persist. In more severe cases there is transient hypothyroidism that usually lasts four to eight weeks. As recovery continues, thyroid follicles regenerate, the colloid is repleted, and normal thyroid function is restored. Persistent or progressive thyroid disease is unusual in contrast to silent thyroiditis, but an occasional patient may develop persistent hypothyroidism whereas 40% of patients with silent thyroiditis have a hypothyroid phase lasting four to 16 weeks, and occasionally persisting indefinitely.

Although clustering of cases of cases has been reported in the past, there has been no proven association with any infectious agent, autoimmune state, or drugs. Our cases occurred between winter and spring and the patients were unrelated; we were unable to establish an etiology. Two of the patients had subacute thyroiditis and three had silent thyroiditis. Cases 4 and 5 became clinically and chemically euthyroid within five weeks and five months respectively. The other three patients are currently in the hypothyroid phase, and two of them are receiving synthroid. Thyroid functions are being monitored with the expectation of restoration of normal thyroid function tests.

These cases serve as a reminder that not all hyperthyroidism is due to Graves' disease or nodular thyroid disease. Consideration of other causes of hyperthyroidism is important before initiating therapy, since the therapeutic modalities (such as radioactive iodine treatment or thioureas) applied to Graves' disease and toxic nodular disease are inappropriate and ineffective in conditions such as subacute thyroiditis. They also emphasize the importance of radionuclear imaging in the diagnostic workup of hyperthyroidism.

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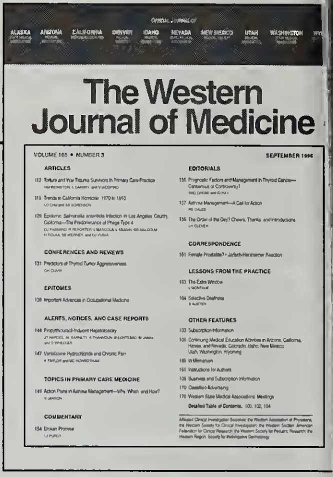

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Important Advances in Clinical Medicine

Internal Medicine

DONALD I. FEINSTEIN, M.D., Section Editor

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in internal medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in internal medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Internal Medicine of the California Medical Association, and the summaries were prepared under the direction of Dr. Feinstein and the Panel.

Mild Cobalamin Deficiency

CLASSICAL cobalamin deficiency poses relatively few diagnostic problems today. The patient has megaloblastic anemia and/or neurological dysfunction, a low serum cobalamin level and cobalamin malabsorption (most often secondary to pernicious anemia, the gastric disease in which intrinsic factor secretion is lost). Attention has shifted recently to the challenge of milder cobalamin deficiency states in which signs such as megaloblastic anemia are not apparent. This is a much more common problem than classical deficiency. This entity has emerged largely because of the application of sensitive metabolic tests to patients. These tests include measuring the metabolites methylmalonic acid (MMA) and homocysteine; deoxyuridine suppression testing of bone marrow cells may be more sensitive than measuring metabolite levels, but it is too cumbersome for clinical use.

Whereas homocysteine levels also become abnormal in folate and pyridoxine deficiencies, MMA elevation is more specific for cobalamin deficiency. However, it must be remembered that levels of both metabolites rise with renal insufficiency, volume contraction, various enzyme defects unrelated to vitamin deficiency, and, in the case of homocysteine, improper collection and processing of blood samples.

What is the role of the metabolite assays in current clinical practice? Although hyperhomocysteinemia of any cause has important associations with vascular disease, the discussion here will be confined to the issue of cobalamin deficiency. Broadly speaking, metabolite assay has two clinical applications in patients with possible cobalamin deficiency.

One application is in the confirmation of clinically suspected cobalamin deficiency whenever standard tests produce ambiguous results. Examples include the patient with megaloblastic anemia or neurologic dysfunction whose normal or borderline cobalamin levels leave one uncertain whether to pursue other explanations instead. Another example is the patient with megaloblastic anemia who has low serum levels of both cobalamin and folate, leaving one uncertain whether the patient has an "artifactually" low cobalamin level due to folate deficiency alone or is deficient in both vitamins. In both examples, abnormal MMA levels would indicate that cobalamin deficiency is indeed present.

The second application is in the patient who has low cobalamin levels but equivocal or absent clinical signs of deficiency. This situation is more common than either classical deficiency or the situation described in the first set of scenarios. It is especially common in older persons, about 10% of whom (ie, about four million Americans) have low cobalamin levels but little or no clinical evidence of deficiency. Evidence from several laboratories indicates that 50%-75% of these elderly patients have meta-

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bolic evidence of cobalamin deficiency that responds to cobalamin therapy (ie, they have mild, preclinical cobalamin deficiency).

The still unresolved question concerning the latter condition is how much diagnostic and therapeutic effort is warranted by biochemical insufficiency alone. It is fair to say that diagnostic attention and a therapeutic trial are due any patient in whom the entity is uncovered because of symptoms, even vague symptoms. Moreover, even if asymptomatic, any patient found to have an underlying malabsorptive cause must be treated with supplements, especially if the cause of malabsorption is irreversible. For example, 1.9% of 729 healthy elderly people in Los Angeles (including about 4% of elderly white and black women) were found to have untreated, unsuspected, and usually asymptomatic pernicious anemia. Like all patients with classical malabsorption, such patients are best treated with parenteral cobalamin, although large oral doses (1,000 μg daily) can be used if necessary. A failure to split cobalamin from its binders in food (food-cobalamin malabsorption), a disorder due to various types of gastric dysfunction including atrophic gastritis and most forms of gastric surgery, is more common than pernicious anemia and has been identified in 30%-40% of patients with low cobalamin levels. Such patients can probably be treated with small oral doses of cobalamin (1-10 μg daily), as can patients with nonmalabsorptive causes of deficiency. Treatment of patients with mild cobalamin deficiency may take on added importance as folate supplementation becomes more widespread in the United States.

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Cardiac Troponins in Patients with Chest Pain

BECAUSE the electrocardiogram is not diagnostic in almost 50% of patients with acute myocardial infarction (MI), biochemical methods have been crucial for detection of MI in this group. Important characteristics of a reliable serum marker of cardiac necrosis include high concentration in the myocardium, absence in noncardiac tissues, rapid release from injured cells and sufficient persistence in the serum to allow detection after an extended interval from the onset of symptoms. For more than two decades, these criteria have been best met by the myocardial band (MB) isoenzyme of creatine kinase (CK), establishing it as the most widely used serum marker of acute MI. Although CK-MB has been useful, its limitations include lack of specificity due to its presence in noncardiac tissues such as small intestine, skeletal muscle, diaphragm, uterus, and prostate and its elevation in renal failure, as well as a pattern of elevation that begins three hours after onset of acute MI and takes up to 12 hours for diagnostic values in many patients. Because CK-MB levels usually return to normal in less than three days in most patients, increased isoenzyme-1 of lactate dehydrogenase (LDH), which also has imperfect specificity but persists for 10-14 days, has been utilized for delayed diagnosis of MI. The limitations of these current biochemical methods have spurred recent interest in new serum markers, much of which has focused on the troponins.

The troponins comprise a protein complex of three subunits that regulates the interaction of actin and myosin in cardiac and skeletal muscle. The subunits are troponin T (cTnT), I (cTnI) and C (cTnC). The aminoacid sequences of cTnT and cTnI (but not cTnC) in cardiac and skeletal muscle differ, allowing for a highly specific monoclonal antibody-based assay for their measurement in serum. Early clinical studies of the troponins in the diagnosis of acute MI have revealed a number of advantages over CK-MB. Serum levels of cTnT and cTnI are very low in normal individuals and have greater relative magnitudes of increase in serum after MI than current markers, facilitating the distinction between normal and abnormal data. The sensitivity of cTnT and cTnI for diagnosing acute MI has been equivalent to or higher than that of CK-MB in most studies. Although the time of initial release of the troponins after MI is similar to that of CK-MB, they remain elevated for up to two weeks. The persistence of troponin elevation after infarction will likely render measurement of LDH-1 obsolete for late detection of MI.

A major advantage of the troponins is their superior specificity over CK-MB, reflected in their lack of elevation by injury of noncardiac tissues. This is well demonstrated by normal cardiac troponin levels in marathon runners, in whom CK-MB levels can be elevated. Specificity of cTnI in acute MI is 85-95%. Although the specificity of cTnT has been reported to be as low as 80% in some studies, this may be due to its ability to detect minimal cardiac damage in some patients currently categorized as having unstable angina. Exclusion of the latter group from these studies has resulted in a marked improvement in specificity of cTnT to 95%. One difference between the two cardiac troponins is elevation of cTnT in uremia, which may be related to its detection of uremic myocardial damage.

A growing role for the cardiac troponins has been in the assessment of patients who present to the emergency department without ST-segment elevation on their electrocardiograms. This group includes patients with non-Q MI, unstable angina, and chest pain of noncardiac origin. Both cTnI and cTnT obtained in the emergency department have been accurate in identifying those patients in whom acute MI was subsequently diagnosed after admission. Furthermore, elevations of the cardiac troponins in patients with unstable angina have been strong predictors of late cardiac events. The availability of rapid, bedside assays for both cTnT and cTnI have made the troponins an important component of the decision-making process for managing the large group of patients presenting to the emergency department with chest pain of uncertain origin. These early studies must be extended to determine whether the troponins provide additional data beyond the clinical evaluation and electrocardiogram in this important patient population.

The troponins possess superior characteristics as serum markers of myocardial damage compared with current methods. They combine a high degree of sensitivity with greater specificity, more sustained elevation and better prognostic value than current markers and they can be measured by a rapid assay. These factors justify their emerging status as the serum markers of choice for assessment of patients presenting with chest pain of possible cardiac origin.

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Factor V Leiden and the Prothrombin Gene Mutation: Two Common Genetic Defects Associated with Thrombosis

MORE than 50% of patients who develop a spontaneous deep vein thrombosis (DVT) will be found to have one or more thrombophilic disorders. The majority of these defects are inherited rather than acquired, in most cases due to a mutation in the gene's coding for either factor V or factor II (prothrombin). The most well known defect, factor V Leiden, causes resistance to the action of activated protein C (APC), one of our most potent natural anticoagulant proteins. This disorder, which involves Caucasians almost exclusively, is thought to have arisen as a single mutation approximately 30,000 years ago. The prothrombin gene mutation was reported in 1996 as a result of ambitious DNA sequencing of the bulk of the prothrombin gene in search of a prothrombotic polymorphism. The mechanism by which the mutation causes thrombosis is under current investigation.

Both of these inherited defects can be easily identified in patients with thrombotic disease. There are two diagnostic tests for factor V Leiden. The best test for screening is the APC resistance ratio, which is available in most Hemostasis and Thrombosis reference laboratories, and costs approximately $60. In the "second generation" assay, the patient's plasma is diluted in factor V-deficient plasma before determination of the clotting time with and without APC. The current assay is highly sensitive and specific, and importantly, can be performed in patients on anticoagulation (both heparin and warfarin), and is not affected by low titer lupus inhibitors. The PCR-based DNA test for the specific factor V Leiden mutation will identify heterozygotes and homozygotes, but is more expensive (eg, $100–150). It should be reserved for patients in whom the screening test is uninformative, or to confirm that patients with low APC resistance ratios (eg, < or = 1.3) are homozygous for the defect. Unfortunately, prothrombin activity assays cannot reliably be used to screen for the prothrombin gene mutation, making DNA testing mandatory.

Both thrombophilic disorders are exceedingly common. Factor V Leiden occurs in 3%-8% of European populations and is found in approximately 15%-20% of patients with a first DVT, and in up to 50% of patients with recurrent venous thromboembolism or women with estrogen-related thromboses. The prothrombin gene mutation is present in 2% of the general population, 6% of patients presenting with a single DVT and up to 18% of patients with a personal and family history of thrombosis.

Because these disorders are so prevalent, they frequently coexist with other hypercoagulable states, greatly magnifying the risks of thrombosis. For example, many cases of factor V Leiden or the prothrombin gene mutation occurring together with hyperhomocysteinemia, antiphospholipid antibodies, or protein C deficiency have been reported, and combined defects are frequently encountered in clinical practice. In general, the risks of future thromboembolism increase exponentially when patients have multiple defects. For example, in the Physicians Health Study, subjects with either factor V Leiden or hyperhomocysteinemia had a three to four-fold increased risk of idiopathic thrombosis. However, when both defects were present, the relative risk soared to 22. There is also a striking increase in thrombotic risk when factor V Leiden is combined with other circumstantial risk factors such as surgery, trauma, or immobilization, or high estrogen states associated with oral contraceptives or pregnancy. There appears to be a synergistic interaction with estrogens, reflected in the greater than 30-fold increase relative risk in factor V Leiden carriers who also use oral contraceptives.

Although both the factor V Leiden and prothrombin gene mutations have been primarily linked to venous thromboembolism, two recent studies reported a nearly four-fold increased risk of MI in young women with other cardiovascular risk factors, particularly smoking. Arterial thromboembolism may also occur in patients with venous thrombosis via a right to left shunt through a patent foramen ovale or other cardiac defect.

What are the implications of these disorders for clinical practice?

Both the factor V Leiden and prothrombin gene mutations, by themselves, are relatively "mild" hypercoagulable disorders. This is illustrated by the observation that many carriers do not experience their first thrombotic episode until an advanced age, and some never develop thrombosis. In the absence of a history of thrombosis, long-term anticoagulation is not routinely recommended since the 1%-2% per year risk of major bleeding from warfarin is greater than the estimated < 1% per year risk of thrombosis in asymptomatic carriers. However, if other circumstantial or hormonal risk factors or other persistent hemostatic defects are present, then the potential benefits from long-term anticoagulation may outweigh the bleeding risks. Ultimately, in the future, identification of one or more hereditary or acquired prothrombotic states will allow accurate prediction of the risk of future thrombosis, making the sometimes difficult decision about long term anticoagulation more rational.

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Prostate Carcinoma: Clarification Through Clinical Insight and Molecular Diagnostics

THE dilemmas surrounding carcinoma of the prostate (CaP) screening and treatment are a source of professional debate and confusion, and fear for patients and their wives. Four recent developments provide guideposts to reduce uncertainty.

First, the epidemic is waning. Predictions by the American Cancer Society of 334,500 cases in 1997 were high; actually fewer than 210,000 cases were diagnosed. The incidence is lower because the earlier diagnosis of preclinical or latent cancers by serum PSA screening has been completed and these patients are thus removed from each year's new count. No prediction is possible of the ultimate level of decline. However, the increase of CaP in men over the age of 70 (years) and our belief that there are environmental factors increasing the incidence of CaP suggests that we will not return to pre- PSA testing levels of the disease.

Second, we know that patient characteristics are important in deciding whether to use PSA to screen for CaP. If men are to benefit from CaP screening and treatment, they must have a reasonable likelihood of surviving more than 10-15 years. Thus, perhaps as important as age exclusion may be the exclusion from PSA testing of men with poor health and/or prospects, eg, heavy cigarette smokers. In addition a brief written informed consent prior to PSA testing describing the consequences of CaP diagnosis may reduce patient interest in the procedure. However, a substantial proportion might choose to proceed with testing, presumably with an improved attitude regarding intervention if and when CaP is found.

Third, modifications of PSA testing designed to improve the predictive value of the test continue to be reported. PSA density, age specific values, and PSA velocity have not been confirmed to enhance specificity and sensitivity. PSA circulates bound to serum proteins. A reduced ratio of free to bound PSA improves the distinction between malignant and benign causes of PSA elevation. CaP can be detected even in men with PSA levels less than 4.0 ng/mL.

Fourth, research may help to distinguish apples from oranges. Although the Gleason score on pathology examination remains the most important predictor of metastatic potential in cohorts of patients, individual variation is sufficient to reduce assuredness that local-regional therapy alone will be curative. Nomograms that combine Gleason score, serum PSA, and clinical stage have been reported to refine the prediction of organ confined disease. As with other aspects of oncology, these nomograms are readily available to patients on the Internet but they have not been validated to improve survival.

There is now a catalog of molecular alterations that are beginning to distinguish familial from sporadic and indolent from progressive cancer, as well as local regional neoplasia from disseminated, and androgen sensitive from androgen insensitive cancer. The locus for a major prostate cancer susceptibility gene resides on chromosome 1. Mutation in the tumor suppressor gene p53 can be identified in 40% of primary CaP and greater than 70%–80% of metastatic CaP cells. Patients at relapse are not human-androgen receptor (hAR) negative but overexpress the hAR protein, a phenomenon that reflects gene amplification.

Alterations in gene expression begin to provide a cohesive explanation for the remarkable variation in the biology of CaP. Patient education will now have to extend from informed consent around PSA testing to the nuances of tumor suppressor genes and hormone receptors.

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Finding the Iron in the Melting Pot— Practical Use of a New Genetic Assay for Hereditary Hemochromatosis

HEMOCHROMATOSIS is a syndrome characterized by excessive iron accumulation. Left untreated, it is associated with progressive dysfunction of multiple organs including the heart, pituitary, pancreas, and liver. Resultant diabetes and cirrhosis account for most of the associated mortality. A genetic basis for many cases of hemochromatosis has long been recognized. Linkage to the region of chromosome 6 harboring HLA genes was demonstrated over two decades ago. The autosomal recessive culprit gene is particularly common in Caucasians of European ancestry, yet is also widely distributed among our heterogeneous American population. The carrier rate in the U.S. is about 10%, most of whom are unaffected heterozygotes. One in every 200–500 Americans has overt disease. Recently, a candidate gene (HLA-H or HFE) associated with the most common form of hereditary hemochromatosis (HH) has been identified. Subsequent studies from Europe and the U.S. have shown that 61%–100% of hemochromatosis patients are homozygous for a single G to A point mutation resulting in the substitution of tyrosine for cysteine (C282Y) in this gene. The identification of this HFE gene represents a molecular genetic *tour de force*, is one of the most important recent developments in medicine, and has led to a commercially available PCR-based assay for the C282Y mutation. How most rationally is clinical practice now altered by this discovery?

The first screening test for hemochromatosis is measurement of transferrin saturation. Values above 60% for men, and 50% for women, will detect most patients. Determination of serum ferritin adds a measurement of iron stores and usually correlates with the extent of hepatic iron content. When serum ferritin is over 400 ng/mL in men (or 200 ng/mL in women), hemochromatosis is the most likely diagnosis, barring other obvious causes of these abnormal iron studies. Pending a consensus on the appropriateness of general population screening (see below), at the very least, these iron studies should be performed in all individuals with chronic hepatitis (especially with coexisting diabetes or heart failure) or a family history of liver disease. Traditionally, a liver biopsy is then recommended. Biopsy also allows quantitative determination of iron content and, when adjusted for age, calculation of hepatic iron index, which to date has been the gold standard of diagnosis. Other possible benefits include assessment of fibrosis, and detection of unsuspected hepatic disease such as unappreciated alcoholism or alpha-one-antitrypsin deficiency.

Could the new genetic test for hemochromatosis avoid the risks of a liver biopsy? If a patient has characteristic abnormal iron studies and is found to be homozygous for the C282Y mutation, the answer is probably yes. The presence of cirrhosis (the most useful prognostic indicator) can usually be diagnosed on other clinical grounds. Present or not, however, phlebotomy would still be recommended. Certainly, the new test should now supplant the use of HLA typing (a far more expensive and less accurate method) to screen relatives of proband cases. The test may also be useful in certain currently challenging clinical scenarios. For example, patients with alcoholic liver disease alone will often have high transferrin saturations. A positive genetic assay could help identify the subset of patients with coexisting HH, a diagnosis currently made only by liver biopsy. Perhaps most importantly, a genetic test for HH offers the best prospect of identifying those individuals at risk even before they accumulate excess iron. Unlike several other genetic tests, an effective treatment for the detected disease is available and can result in a normal life span.

What does this new test not do? It will not detect nonhereditary forms of excess iron accumulation such as African (Bantu) iron overload or that secondary to ineffective erythropoiesis. It will also not identify the small but significant percentage of patient clusters who demonstrate classic presentation and/or patterns of inheritance, but yet do not harbor the C282Y mutation. Presumably they have a yet unidentified different mutation. Finally, the new genetic test should not be the initial screening test—a role still best filled by the combination of transferrin saturation and serum ferritin.

To thicken the plot, a second mutation in the HFE gene resulting in an aspartic acid substitution of histadine (H63D) has also been identified. Although still somewhat controversial, some studies showed the compound heterozygotes C282Y/H63D are at increased risk with approximately 1% developing clinical hemochromatosis; a four-fold increased risk was associated with H63D homozygosity. The commercially available genetic assay for HH does not currently test for the H63D mutation. In addition, both C282Y and H63D mutations are found in increased frequency in yet another iron loading disease, sporadic porphyria cutanea tarda (PCT). Up to 21% of PCT patients in Britain are C282Y homozygotes. In contrast to the usual HH, C282Y homozygotes presenting as PCT can live for over 60 years without developing iron overload. Hepatic iron storage in patients with PCT is usually normal and <10% have increased iron storage reaching the lower range of hemochromatosis. Nevertheless, it has been recommended that all patients with PCT should also be tested for HFE, and C282Y homozygotes treated with phlebotomy (rather than medically with chloroquine).

Finding the excessive iron in patients and their families *before* the development of irreversible complications remains the most important challenge in the successful treatment of hemochromatosis. The task is made easier by the new test for C282Y mutations in the HFE gene. Such a test can be used to confirm HH in a patient with increased iron storage and to screen family members. It may also bolster already rational calls for screening of the general population, which has even been shown to be cost-effective—a so popular criterion these days. The cornerstone of any such program and initial diagnosis, however, remains simple serum iron studies. Certainly, the recent flurry of exciting research should rekindle a requisite high index of suspicion for such a prevalent, potentially devastating and yet treatable disease.

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Homocysteine and Vascular Disease: Emerging Connections

IT is not well established that hyperhomocysteinemia—sustained elevation above normal of plasma homocysteine—is an independent risk factor for thrombosis and premature vascular disease. Whether homocysteine is pathogenetically related or incidental in this association and whether lowering of homocysteine levels ameliorates the cardiovascular risk have yet to be determined.

Hyperhomocysteinemia due either to inborn errors of metabolism or to nutritional deficiency of the vitamins involved in homocysteine metabolism is associated with precocious atherosclerosis and both arterial and venous thrombosis. Predominant among the causes of mortality and major morbidity is thromboembolism, followed by cerebrovascular accident, peripheral arterial thrombosis, and myocardial infarction.

Hyperhomocysteinemia, regardless of its cause, is an independent risk factor for stroke, coronary, or peripheral artery disease. For every increase in total plasma homocysteine of 5 μmol/L, there is a corresponding increase of about 40% in the relative risk of developing coronary artery disease. This increase is comparable to the risk associated with the same proportional increment in cholesterol and equates homocysteine with cholesterol as risk factors for ischemic heart disease. Moreover, the relative risk/odds for cerebrovascular and peripheral arterial disease associated with elevated homocysteine is even greater than it is for coronary artery disease. The European Concerted Action Project on Hyperhomocysteinemia found that subjects in the top quintile for plasma homocysteine had a relative risk for vascular disease of 2.2 compared with the lower four quintiles, and the authors concluded that plasma homocysteine not only confers an independent risk of vascular disease similar to that of smoking or hyperlipidemia but also substantially increases the risk associated with smoking or hypertension.

The amino acid homocysteine arises entirely from the metabolism of dietary methionine and is normally present in the plasma at low concentrations (5–15 μmol/L). Metabolic traffic of homocysteine occurs along two major pathways that lead either, via remethylation to methionine or, through transsulfuration, to cysteine. These pathways are under tight metabolic control and involve several enzymes that require folate, cobalamin, or pyridoxine as cofactors. Perturbation of homocysteine metabolism can result from inherited or nutritional disorders or a combination of both.

Whereas severe degrees of hyperhomocysteinemia (>50 μmol/L) are usually the result of homozygosity for inborn errors of metabolism, mild (15–25 μmol/L) or moderate (25–50 μmol/L) degrees of hyperhomocysteinemia are more commonly the result of acquired disorders. The most frequent causes are deficiencies of one or more of the three vitamins that are required as cofactors or substrates for homocysteine metabolism. Serum homocysteine levels show a significant inverse correlation with both serum cobalamin and serum folate, even among the normal population, and even individuals with low-normal folate or cobalamin concentrations may display elevated levels of homocysteine. Heterozygosity for mutant forms of key enzymes in the homocysteine metabolic pathways may have a high frequency in certain populations. Heterozygosity for the methylenetetrahydrofolate reductase (MTHFR) mutation alone does not appear to be associated with increased risk of vascular disease, but its coexistence with hemizygosity for other genetic defects known to predispose to thrombosis, such as factor V Leiden, confers increased risk of occlusive vascular disease. Moreover, hyperhomocysteinemia and the risk of vascular occlusion in MTHFR mutants is mitigated by adequate folate status.

The identification of hyperhomocysteinemia usually takes place through simple measurement of plasma levels of the compound. However, even when basal homocysteine levels are within the normal range, derangements in homocysteine metabolism may be present and may be uncovered by determining peak plasma homocysteine levels following administration of an oral methionine load. In general, impairment of the remethylation pathway is more likely to result in increased fasting levels of homocysteine, whereas transsulfuration pathway defects are more often associated with abnormal responses to methionine loading. Plasma homocysteine should be measured as part of any assessment of cardiovascular risk profile, particularly in individuals deemed to have sustained a precocious or unexplained vascular occlusive event.

Varying degrees of hyperhomocysteinemia occur in patients with chronic renal disease. It is likely that this may contribute to the high prevalence of vascular disease in patients with chronic renal insufficiency.

The risk of multiple vascular occlusive complications attributable to homocysteine is indicative of a profound disruption of normal endothelial cell function, platelet function, or blood coagulation pathways. However, the mechanism whereby homocysteine produces these effects remains obscure.

There is clear evidence that homocysteine levels can be lowered by administration of supplemental folate, with or without pyridoxine. What is not yet established is whether lowering of homocysteine by increased intake of these vitamins results in a diminution of cardiovascular risk. Recently published data strongly support a protective role for high folate and vitamin B6 intake against ischemic heart disease. The prospect of modifying risk of cardiovascular disease in the general population by simple nutritional intervention is appealing and could constitute a substantial advance in the control of a major cause of morbidity and mortality worldwide.

Fortuitously, initiatives have been launched recently in the U.S.A. and elsewhere to fortify the diet with folic acid as a means to reduce the prevalence of neural tube defect in pregnancy. This nutritional modification of the population-at-large could potentially have a salutary effect on the overall prevalence of ischemic vascular disease.

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Follow-up Testing After Cancer Treatment: Is It Indicated?

ADVANCES in surgery, radiation therapy, and chemotherapy have led to an increasing number of cancer patients who are rendered free of disease and potentially cured. It is one of the cruel realities of cancer that many of these patients will relapse. Hence the question of what is the appropriate follow-up of cancer patients after potentially curative treatment. Several surveys have documented that follow-up testing in the form of physician visits and radiographic and laboratory tests is common. An increasing and, indeed, overwhelming, body of literature indicates that much of this testing is unnecessary and can be eliminated.

Four general principles should guide the selection of tests utilized to evaluate patients after potentially curative therapy of cancer:

1. The interval between examinations and duration of testing should be consistent with the maximal risk of recurrence and the natural history of the tumor.
2. The tests should be directed at the most likely sites of recurrence and should have a high predictive value.
3. Therapy should be available that will result in cure, significant prolongation of life, or palliation of symptoms. The initiation of earlier therapy should improve the outcome compared with therapy given when the patient becomes symptomatic from the cancer.
4. The increased risk of second malignancy, both in the primary site and in other tissues in which there is increased risk, should also guide the ordering of tests. Malignant and nonmalignant complications of therapy must also be considered. Such testing should be performed with a frequency and duration consistent with the nature of the risk.

Testicular cancer is the disease with the clearest indication for intensive testing. In this disease the presence of easily determined serum markers, predictable patterns of recurrence, and highly effective therapy mandate close surveillance after initial therapy. In contrast, intensive surveillance following treatment of localized breast cancer has failed to demonstrate any improvement in outcome in terms of quality or quantity of life. In two randomized controlled trials, over 2,500 patients were randomized between an "aggressive" follow-up regimen of frequent chest x-rays, bone scans, serum chemistries, and other tests *vs* a "conservative" strategy of physician evaluations and yearly mammography. In both of these trials and in numerous retrospective studies, 70%–90% of patients who relapsed presented with symptomatic disease. Less than 10% of recurrences were detected exclusively through laboratory or radiologic testing. These trials and studies have led to guidelines by the American Society of Clinical Oncology that recommend a limited degree of follow-up testing which would consist primarily of physician evaluations and yearly mammography. Though the data are retrospective, the situation for a diverse group of both common and uncommon malignancies, including cancers of the lung, colon, prostate, and Hodgkin's and non-Hodgkins lymphoma, is similar to that of breast cancer, ie, most laboratory and radiologic testing appears futile. Only in Hodgkin's disease does routine radiologic testing (a periodic chest x-ray film) afford benefit. Routine complete blood counts and serum chemistries are rarely useful. The role of carcinoembryonic antigen and prostate specific antigen in the follow-up of colon and prostate cancer, respectively, remain to be determined.

A frequently asked question about this subject involves patient expectations. Patients naturally request information about "what is being done to follow my cancer?" What little objective information exists indicates that patients have unrealistically high expectations regarding the accuracy of laboratory and radiologic testing and unrealistically low expectations regarding the use of the history and physical examination in the detection of recurrence. In the only study of its type, a survey of breast cancer patients free of disease found that 92% of patients believed that aggressive testing in the form of blood tests and x-ray studies improved outcome. In one of the randomized studies of breast cancer, randomizing between "aggressive" and "conservative" follow-up testing quality of life was ascertained. There were no differences in terms of emotional well being, body image, social function, satisfaction with care, or overall health measures.

The economic consequences of a policy restricting testing to those evaluations likely to influence outcome as determined through prospective trials or large retrospective series are profound. Modeling by ourselves and others indicates that savings in the hundreds of millions to billions of dollars may be realized. These savings could be obtained without compromise in the quality of care and without restriction of access. Indeed, the policy of limited follow-up testing places a premium on physician evaluation of the patient and education.

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Noninvasive Positive Pressure Mechanical Ventilation

NONINVASIVE mechanical ventilation refers to the technique of supporting alveolar ventilation without the use of an artificial airway in the trachea. Although mechanical ventilation with endotracheal intubation is a successful means of providing ventilatory support, recent advances in the design of nasal and facial masks, together with the development of newer styles of ventilators, have widened the options available to patients with respiratory failure. Potential advantages to avoiding endotracheal tubes include improved comfort, preservation of speech and swallowing, decreased risk of infectious complications, and decreased laryngeal injury. However, not all patients with respiratory failure are candidates for noninvasive techniques. Careful selection of patients and equipment is necessary for success.

A variety of types and sizes of nasal and facial masks are now available for use, allowing a comfortable fit for most patients. The mask should fit snugly, while avoiding excessive pressure on the skin; small air leaks around the mask are acceptable. Nasal masks permit speech, eating, and expectoration without removal of the mask. However, patients in respiratory distress who mouth breathe may need a full face mask. Gastric distention is rarely a problem when the applied pressure is less than 25 cm H_2O. A nasogastric tube for gastric decompression need not be placed routinely.

Noninvasive positive pressure ventilation (NPPV) can be provided by standard volume-cycled or pressure-controlled ventilators or bilevel positive airway pressure ventilators (bilevel PAP). Advantages of standard ventilators include a broader range of ventilation capacity, the ability to deliver higher oxygen concentrations, and the presence of sophisticated monitoring devices and alarms. Pressure-support and pressure-controlled modes appear to be the most successful settings when used for NPPV. However, standard ventilators are expensive, complex, and need a high-pressure gas source (50 psi), which limits their use outside the intensive care unit. For these reasons, bilevel PAP has become a popular means of delivering noninvasive ventilation. These less expensive machines cycle between different positive inspiratory and expiratory pressures, either in response to a patient's respiratory efforts, or at fixed rate set by the clinician. Disadvantages of the currently available bilevel PAP machines include their inability to provide high oxygen concentrations and limited monitoring and alarm capabilities.

NPPV appears to benefit over 50% of patients with acute respiratory failure who are cooperative, hemodynamically stable, not severely hypoxemic, can protect their airway, and are able to tolerate a nasal or facial mask. Patients suffering from exacerbations of chronic obstructive pulmonary disease (COPD) appear particularly well-suited for NPPV, with studies suggesting a substantially decreased need for endotracheal intubation. Noninvasive ventilatory techniques have been very successful for many patients with chronic respiratory failure due to restrictive chest wall diseases, certain neuromuscular diseases, and hypoventilation syndromes. Some patients with chronic hypercapnea due to COPD also appear to benefit. For many patients with chronic respiratory failure, intermittent NPPV, often for only a few hours each night, can improve daytime gas exchange. Possible reasons for the benefit in these patients include intermittent respiratory muscle rest, improvement of respiratory compliance by correction of microatelectasis, or resetting of the respiratory center's sensitivity to CO_2.

In summary, NPPV is a useful modality for selected patients with acute or chronic respiratory failure. This technique can provide ventilatory support while avoiding many of the disadvantages of endotracheal tubes and tracheotomies. However, time may be wasted if NPPV is begun in inappropriate patients rather than proceeding directly to mechanical ventilation using endotracheal intubation.

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Treatment of Gastroesophageal Reflux Disease—1998

THE goals of therapy for gastroesophageal reflux disease (GERD) are to relieve symptoms, heal damaged esophageal mucosa, prevent complications, and maintain remission. Effective medical therapy can now achieve all of these goals in the vast majority of patients. Additionally, the introduction of laparoscopic fundoplication has renewed the interest in surgery as a way to achieve these goals, and is an option for patients who prefer an alternative to medication.

Most GERD patients have intermittent reflux symptoms, do not have significant esophagitis, and are unlikely to develop complications. For these patients life-style modifications such as dietary changes, elevation of the head of the bed, avoidance of early recumbency after meals, and discontinuation of smoking, alcohol, and irritant medications may be the only therapy that is necessary.

Antacids may be helpful, but they are neither effective nor cost-effective in patients with daily symptoms or significant endoscopic esophagitis.

For patients with more severe or more frequent symptoms of reflux, H2 receptor antagonists may be added to life-style modifications. Therapy for six to 12 weeks effectively relieves symptoms of reflux and heals esophagitis in about 50% of patients, and maintains remission in about 25% of patients. For severe esophagitis, it is generally more cost-effective to add another agent or to switch to a proton pump inhibitor instead.

Promotility agents may also be used to manage GERD. Cisapride effectively relieves nocturnal heartburn in up to 50% of patients and is as effective as ranitidine in healing mild-to-moderate esophagitis. Metoclopramide may improve symptoms of reflux, but does not heal esophagitis, and should seldom be used because of its significant side effects.

Proton pump inhibitors are far more effective than H2 receptor antagonists at suppressing acid secretion. In patients with mild to moderate esophagitis, omeprazole or lansoprazole control GERD-related symptoms more effectively than H2 receptor antagonists and achieve healing rates of 80% to 100% within eight weeks. Severe cases may require higher doses. Aggressive acid suppression with proton pump inhibitors also improves reflux-related dysphagia and may prevent or delay stricture formation. Significant side effects are uncommon. Most patients with significant esophagitis will relapse when therapy is discontinued, and maintenance therapy with proton pump inhibitors may be indicated. In a recent large prospective study highest remission rates were found in patients on combined omeprazole and cisapride (89%), followed by omeprazole (80%), ranitidine plus cisapride (66%), cisapride (54%), and finally, ranitidine (51%). *Helicobacter pylori* infection itself is not thought to be an important cause of GERD, and eradication of this infection, if present, is not necessary in the treatment of GERD.

Ironically, during the same time that proton pump inhibitors came into common use, surgery for GERD also increased due to the introduction of laparoscopic fundoplication. First performed in the early 1990s, the procedure is now commonly performed at many medical centers throughout the country.

Laparoscopic fundoplication closely approximates the procedure performed over many years by laparotomy or thoracotomy. Both a "complete" fundoplication, sometimes referred to as "Nissen fundoplication," as well as a "partial" fundoplication, may be performed laparoscopically. Partial fundoplications augment lower esophageal sphincter pressure less than complete fundoplications and may be preferred in patients with significant impairment of esophageal peristalsis. More complex operations, in which the length of the esophagus is augmented by dividing a portion of the stomach, may also be performed, but wide experience with these is lacking.

Patients being considered for surgery for GERD should undergo endoscopy with biopsies, 24-hour pH monitoring, and esophageal manometry. Endoscopy with biopsy is necessary to look for esophagitis or the premalignant condition of Barrett's esophagus. Biopsies should be performed because short segments of Barrett's esophagus may not always be grossly apparent. A 24-hour pH is performed to confirm that symptoms are caused by reflux of gastric contents and to document pathologic reflux in patients with atypical symptoms. Manometry is performed to assess esophageal motor function. Patients with impaired peristalsis are at increased risk for the development of dysphagia if a complete fundoplication is performed, and in these patients a partial fundoplication may be preferred. Occasionally, manometric findings may suggest an underlying collagen vascular disease (eg, scleroderma), and in some instances the manometric findings may contraindicate an antireflux operation. Some patients with early achalasia, for example, may complain of heartburn, and an antireflux procedure would be inappropriate. A barium swallow is expected by many, but not all surgeons, to assess the size of a hiatal hernia and to exclude anatomic surprises, such as diverticulae or esophageal shortening. Long-term follow-up with laparoscopic fundoplications is not yet available, but it is reasonable to expect good or excellent results in 90% of patients at 10 years.

Previous studies have demonstrated the superiority of antireflux surgery performed by laparotomy to that of medical management with H2 blockers. To date, however, there is no direct comparison of the results of laparoscopic fundoplications with proton pump inhibitors nor are there any good cost data to compare the two approaches. Indications for surgery, therefore, are not well defined. Complications of GERD are seldom fatal, and in most patients they may be prevented and symptoms much improved with medications. Indeed, symptoms that are not significantly improved by aggressive medical management may not actually be from gastroesophageal reflux, and may not be relieved by surgery. Most patients are referred for surgery because of their desire not to be medication-dependent. Long-term follow-up studies will be necessary to determine the role of laparoscopic surgery in the modern-day management of GERD.

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β-Adrenergic Blockers in the Management of Heart Failure

DESPITE more than two decades of experience, there remains a hesitation to incorporate β-adrenergic blocker therapy into the management of patients with heart failure. This is a consequence of a misconception: β-adrenergic blockers are contraindicated in a condition characterized by inadequate cardiac contractility because they weaken the heart contractions. This reasoning would be justified if heart failure were simply a matter of disturbed pump function and altered hemodynamics. It is not.

Cardiac injury results in a reduction of myocyte mass and contractile force, leading to impaired hemodynamics and diminished forward cardiac output. Compensatory mechanisms are quickly brought into play: activation of the sympathetic nervous system and the renin-angiotensin-aldosterone hormonal axis. Protracted neurohormonal activation is detrimental because it contributes to ventricular dilatation and remodeling, increased wall stress, down regulation of β-l-adrenergic receptors, desensitization of β-adrenergic receptors, and, therefore, additional myocyte loss, increased myocardial energy demands, impaired diastolic function and filling, enhanced resistance to forward blood flow from systemic vasoconstriction, and promotion of arrhythmogenesis and sudden death. Elevated levels of norepinephrine, renin, and angiotensin-II correlate with poor survival and heart failure. Progression of heart failure is a consequence of neurohormonal overload, not the initial cardiopathic injury.

Interruption of the detrimental effects of these hormones should benefit patients with chronic heart failure. Angiotensin-converting enzyme inhibitors (ACE-I) are now established drugs in the management of heart failure. They improve hemodynamics, improve heart failure symptoms, slow heart failure progression, and reduce mortality. β-adrenergic blockers should produce similar benefits. β-adrenergic blockers may impart benefits by their antiarrhythmic properties and, therefore, reduce sudden death. But, since ACE-inhibitors are now standard care for heart failure, the benefits of β-adrenergic blockers must be ascertained in the circumstance of being added to ACE-inhibitor therapy. Even if β-adrenergic blockers are equivalent to ACE-inhibitors, they could appear neutral when added to ACE-inhibitors unless their benefits are achieved by alternate mechanisms not already affected by inactivation of the renin-angiotensin axis. The choice of β-adrenergic blockers is difficult because using the optimal agent is critical to establishing the benefits (or lack thereof) of β-adrenergic blockade in heart failure.

First generation β-adrenergic blockers are not selective for β-1 or β-2 receptors and include drugs such as propranolol and timolol. These agents have been avoided in heart failure for fear that β-2 blockade would promote systemic vasoconstriction. Second generation β-adrenergic blockers are selective for β-1 receptors and do not have ancillary properties. These include metoprolol, atenolol, bisoprolol, and betaxolol. Some of these have been extensively tested in heart failure. Metoprolol, when added to ACE-inhibitors, significantly decreases heart rate and pulmonary capillary wedge pressure and significantly increases left ventricular ejection fraction, cardiac index, exercise capacity, and improves heart failure symptoms and quality of life. Withdrawal of metoprolol from stable heart failure patients has produced hemodynamic decompensation.

Third generation β-adrenergic blockers have ancillary cardiovascular activity beyond β-adrenergic blockade. These ancillary actions include α-blockade (carvedilol and labetolol), intrisic sympathomimetic effects (pindolol), nonspecific systemic vasodilation (bucindolol), type 3 antiarrhythmic activity (sotalol), or antioxidant effects (carvedilol). Carvedilol has been tested in mild to moderate heart failure. It has been shown to produce all the benefits of metoprolol and bisoprolol, but in addition has been shown to reduce mortality compared to a placebo in patients on ACE-inhibitor therapy.

Patience is important in the application of β-adrenergic blockers to patients with heart failure. Negative effects on contractility and vasomotor regulation can cause acute decompensation. β-adrenergic blockers must therefore be initiated at very low doses and slowly titrated upwards. Even so, an average of 7% (0% to 42%) of patients with mild to moderate heart failure will not tolerate the slow titration of second- or third-generation β-adrenergic blockers. For those who tolerate them, the hemodynamic and symptomatic improvements generated by β-adrenergic blockers are usually evident within one to three months of their initiation and are sustained for at least one year (perhaps longer).

The weight of the above evidence argues that selected β-adrenergic blockers should be added to stable patients with mild to moderate heart failure on ACE-inhibitors, digitalis, and diuretics. β-adrenergic blockers will improve heart failure symptoms, improve exercise capacity, and slow heart failure progression leading to better and improved survival. The next step is to determine whether patients with severe heart failure can tolerate β-adrenergic blockers and if so, whether they will enjoy similar benefits.

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Diabetes in Older Persons: Special Considerations

AT least 40% of all people aged 65 years and older have diabetes or impaired glucose tolerance: 10% are already diagnosed as diabetic, 10% have diabetes and are undiagnosed, and a further 20% have impaired glucose tolerance. There are several types of diabetes; the two major types are type 1 (patients are usually close to ideal body weight, ketosis prone, and cannot survive without insulin replacement), and type 2 (the majority are overweight, ketosis resistant, and can survive without insulin replacement, although insulin may improve glycemic control) diabetes mellitus. The majority of older persons have type 2 diabetes. Obese elderly type 2 diabetics have adequate circulating insulin, but marked resistance to insulin-mediated glucose disposal. Lean elderly type 2 diabetics have a profound impairment in glucose-induced insulin release but mild resistance to insulin-mediated glucose disposal.

Blood glucose levels increase slightly but significantly with age: fasting blood glucose concentrations increase by 1 mg/dL (0.055 mmol/L) per decade, and blood glucose levels 1-2 h after an oral glucose load increase by 6.8-13.0 mg/dL (0.38-0.72 mmol/L) per decade. The major defect responsible for this "glucose intolerance of aging" is peripheral tissue insulin resistance secondary to a defect in insulin receptor function at the postreceptor level. The extent of this age-related glucose intolerance varies with the population studied, and is reported to be minimal when moderated by exercise, diet, and diabetogenic drugs. Therefore the otherwise "inevitable" glucose intolerance of aging may be accentuated by factors other than biologic aging per se, and modifications in reversible factors including obesity, physical activity, and medications may postpone or ameliorate the evolution of the glucose intolerance of aging to diabetes.

The American Diabetes Association's Expert Committee on the Diagnosis and Classification of Diabetes Mellitus has recommended three possible ways to diagnose diabetes: 1) a fasting plasma glucose of >126mg/dL (7.0 mmol/L) after no caloric intake for at least eight hours), 2) a casual plasma glucose (taken at any time of day without regard to time of last meal) ≥ 200 mg/dL (11.1 mmol/L), with the classic diabetes symptoms of increased urination, increased thirst, and unexplained weight loss, or 3) an oral glucose tolerance test (OGTT) value ≥ 200 mg/dL in the two-hour sample. Any of these tests need to be confirmed on a subsequent day in order to verify the diagnosis. An additional recommendation is to screen all adults over 45 years of age at three-year intervals. Epidemiological data suggest that retinopathy begins to develop seven years before the clinical diagnosis of type 2 diabetes. Also, because hyperglycemia in type 2 diabetes causes microvascular diseases and may cause or contribute to macrovascular disease, undiagnosed type 2 diabetics are at increased risk for coronary heart disease, stroke, and peripheral vascular disease. Earlier detection and treatment may reduce both the severity and complications of diabetes.

Classic diabetes symptoms—increased urination, thirst, and unexplained weight loss—are not always apparent in the older diabetic. The clinical presentation is often insidious and asymptomatic. Changes in behavioral, cognitive, or functional status may include falling, urinary incontinence, agitation, dementia, delirium, or depression. Acute intercurrent medical illnesses such as urinary tract infection, pneumonia, myocardial infarction, or stroke can exacerbate a baseline glucose intolerance, making an individual with impaired glucose tolerance meet the diagnostic criteria for diabetes. Often treatment of the underlying health problem can reduce this exacerbation glucose intolerance, allowing a return to diabetes management with diet and physical activity alone. Many medications have been associated with altering glucose homeostasis, and sometimes adjusting the drug regimen may obviate the need for oral hypoglycemic or other pharmacologic intervention.

An individualized and comprehensive care plan is recommended because older diabetics are a heterogeneous group. Some live independently; some live in nursing homes. Often there are associated comorbid and intercurrent health problems and varying cognitive and functional abilities. The current dilemma is to avoid both undertreatment and associated risks of long-term complications, and overtreatment with risks of immediate adverse reactions, especially hypoglycemia. Written instructions for patients and caregivers are important, especially in view of poor recall of verbal instructions.

When setting treatment goals, individual patient characteristics should be considered: capacity to understand and carry out the treatment regimen, risk for severe hypoglycemia, as well as other factors that may increase risk or decrease benefit, such as end-stage renal disease or advanced cardiovascular or cerebrovascular disease. The ultimate goals are relief of symptoms, maintenance of well being, and the prevention of complications. These require glycemic control, blood pressure regulation, and monitoring of serum lipid and lipoprotein levels. Age alone should not be used as an excuse for compromised blood glucose control. The risk of recurrent hypoglycemia may outweigh the benefits of tight control in those elderly with reduced life expectancy and diminished quality of life. However, persistent hyperglycemia can impair defense against infection, decrease the pain threshold, and worsen neuropathic pain.

Nonpharmacologic therapy, including diet and physical activity, remains the cornerstone of management. Weight reduction should not be suggested in those over 70 years of age unless they are at least 20% above desirable weight. The restriction of dietary free sugars can be valuable in maintaining normoglycemia. Do not discount an exercise regimen. Although not all seniors are able to do 20 to 30 minutes of brisk walking three times per week, a graded physical activity program should be devised within the individual's capabilities.

Oral hypoglycemic agents are often used when an adequate trial of diet and physical activity fail to bring the blood glucose toward normal and the patient becomes symptomatic. Metformin can be used in the relatively obese geriatric patient with no contraindications, for often there is an associated weight loss, which in conjunction with diet and physical activity, may allow withdrawal of the medication. Instead of advanced age alone, renal function and/or any other age-related factors likely to contribute to lactate overproduction should be the basis for choosing metformin therapy. In older persons, chlorpropamide use is associated with a high risk for hypoglycemia. Among the commonly used second-generation sulfonylureas, hypoglycemia is reportedly more frequent with glyburide than with glipizide.

Many older diabetics may already use insulin. Approximately 10% of those who develop diabetes over the age of 70 years have type 1 diabetes mellitus. Often in the setting of acute intercurrent illness, type 2 diabetics are managed with insulin. They can frequently switch to an oral agent after the acute episode subsides, thus avoiding potential adverse effects of insulin, including hypoglycemia and weight gain. Hypoglycemic episodes including coma may be in the range of 20% per year when insulin is started after the age of 70 years.

In summary, aging increases the likelihood of type 2 diabetes mellitus with all of its inherent risks. Life-style changes, treatment of underlying illnesses, and modifications of drugs may diminish glucose intolerance. When these efforts fail, oral hypoglycemic drug therapy is recommended, using biguanides and sulfonylureas, either alone or in combination, and finally insulin when these measures are not effective.

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CONTINUED ON NEXT PAGE

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Sildenafil: A New Therapy for Erectile Dysfunction

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SILDENAFIL, (Viagra™, Pfizer Inc.) an oral therapy for erectile dysfunction, was approved by the FDA in March 1998. Sildenafil improves erectile function in men with organic or psychogenic impotence by enhancing smooth muscle relaxation in the corpus cavernosum.[1]

Pharmacology

Sildenafil is a selective inhibitor of cGMP-specific phosphodiesterase type 5 (PDE5). The physiology of penile erection involves the release of nitric oxide (NO) in the corpus cavernosum during sexual stimulation.[1,2] NO activates guanylate cyclase, which increases levels of cGMP, resulting in smooth muscle relaxation and inflow of blood.[1–3] Sildenafil inhibits the secretion of PDE5, the predominant phosphodiesterase isoenzyme in the human corpus cavernosum, which is responsible for the breakdown of cGMP.[2] Inhibition of PDE5 results in increased cGMP, presumably leading to enhanced vasodilation and improved erectile function.[1] In the absence of sexual stimulation, sildenafil at recommended doses has no effect.[1]

In vitro studies show that sildenafil has high selectivity for PDE5 when compared to other known phosphodiesterases.[1] For example, sildenafil's selectivity is approximately 4,000-fold greater for PDE5 than for PDE3, which is involved in cardiac contractility.[1] Sildenafil is 10 times as potent for PDE5 as PDE6, which is found in the retina; sildenafil's adverse effect on vision in some patients may be related to this partial inhibition of PDE6 (see adverse reactions).[1]

Pharmacokinetics

Sildenafil is approximately 40% bioavailable after oral administration.[1] Peak plasma concentrations are observed at 30 to 120 minutes after oral dosing (fasting state).[1] The rate of absorption is reduced when sildenafil is administered with a high-fat meal, with mean reduction in Cmax of 29% and a mean delay in Tmax of 60 minutes.[1] The mean volume of distribution at steady state is 105L, indicating distribution into the tissues.[1] Both sildenafil and its active metabolite are approximately 96% protein bound.[1]

Sildenafil is cleared primarily by the liver (mainly cytochrome P450 3A4, and less by 2C9).[1] Sildenafil is demethylated to an active metabolite which has PDE selectivity similar to that of the parent drug and an *in vitro* activity of about 50% of the parent drug.[1] The half-life for both is about four hours.[1] Sildenafil is excreted as metabolites predominately in the feces and to a lesser extent in the urine.[1]

No significant pharmacokinetic differences were noted between healthy volunteers and the patient population.[1] However, significant differences were noted in geriatric, renally impaired, and hepatically impaired populations (see Administration and Dosage).[1]

Clinical Trials

Two clinical trials have been published to date; these studies are summarized below. According to the manufacturer, sildenafil has been evaluated in 21 randomized, double-blind, placebo-controlled trials in more than 3,000 patients. Patients were treated for up to six months; all 21 studies showed statistically significant improvement with sildenafil compared to placebo.[1] One study examining the

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time-course of effect showed response up to four hours after oral administration, but response was diminished compared to two hours.[1]

Sildenafil (25 mg and 50 mg) was tested in a randomized, double-blind, placebo-controlled crossover study in 12 men (aged 36 to 63 years) with erectile dysfunction of no established organic cause.[2] Efficacy was measured by both penile plethysmography (RigiScan) during visual sexual stimulation (two hours) and diary recording of erectile activity during one week (once daily dosing for seven days). Sildenafil was significantly more effective than placebo at both doses during both phases of the study. The mean (95% CI) total number of erections during one week of treatment with sildenafil was 6.1 (3.2-11.4) compared with 1.3 (0.5-2.7) on placebo (P=0.005). However, there was a trend toward a "sequence effect" for the total number of erections (P=0.059); patients who received placebo after sildenafil had fewer erections (3.6; 1.0-10.9) than patients who received sildenafil after placebo (10.1; 1.3-13.3). Limitations of this trial include small sample size, short duration of treatment, and unexplained etiology of erectile dysfunction.[4]

In two sequential randomized, double-blind, placebo-controlled studies, sildenafil efficacy was evaluated in 861 men aged 18 years or older with erectile dysfunction of various etiologies (70% organic, 11% psychogenic, and 18% mixed).[5] Efficacy was assessed by a sexual function questionnaire (the International Index of Erectile Function—IIEF), a patient log, and a global efficacy question.[5] The two principle questions of the IIEF measured 1) the ability to achieve erections sufficient for sexual intercourse and 2) the maintenance of erections after penetration. Other aspects of sexual function were assessed, such as orgasm, desire, and overall sexual satisfaction.

In the 24-week dose-response part of the study, 532 men were treated with sildenafil 25 mg, 50 mg, or 100 mg, or placebo.[5] Patients were instructed to take sildenafil (or matching placebo) approximately one hour before planned sexual activity. Fifty-six percent, 77%, and 84% of patients treated with 25 mg, 50 mg, and 100 mg sildenafil respectively reported improved erections compared to 25% of patients on placebo (P<0.001 for treatment effect). Increasing doses of sildenafil were associated with improved erectile function (P values for increases in scores for questions about achieving and maintaining erections were <0.001). In the flexible dose-escalation portion of the study, 329 different men were randomized to sildenafil 50 mg or placebo for 12 weeks. At each follow-up visit, the dose could be increased or decreased by 50% based on therapeutic response and adverse effects. During the last four weeks of treatment, 69% of all attempts at sexual intercourse were successful in the sildenafil group, compared to 22% of attempts in the placebo group (P<0.001). At the end of the study (12 weeks), the percentage of men taking 25 mg, 50 mg, and 100 mg of sildenafil were 2%, 23%, and 74%, respectively.

Sildenafil was studied in various patient populations, including patients with cardiac disease, peripheral vascular disease, diabetes mellitus, depression, radical prostatectomy, transurethral resection of the prostate, and spinal cord injury, and in patients taking antidepressants/antipsychotics and antihypertensives/diuretics.[1] Sildenafil demonstrated efficacy regardless of baseline severity, etiology, race, and age.[1] In a randomized, double-blind, flexible-dose, placebo-controlled study in 268 patients with erectile dysfunction attributable to complications of diabetes mellitus, 57% of patients on treatment reported improved erections compared to 10% on placebo (success rate 48% *vs* 12%).[1] A small crossover study published in abstract form showed similar results in patients with diabetes.[6] In a randomized, double-blind, flexible-dose, placebo-controlled study in 178 patients with erectile dysfunction due to spinal cord injury, 83% of patients on treatment reported improved erections *vs* 12% on placebo (success rate 59% *vs* 13%).[1] A small crossover trial in patients with erectile dysfunction due to traumatic spinal cord injury demonstrates similar efficacy rates.[7] Across all trials, sildenafil improved the erections of 43% of radical prostatectomy patients compared to 15% on placebo.[1] (More detailed information for this patient population is not available at this time.) In 328 patients with psychogenic impotence, 84% reported improvement with sildenafil *vs* 26% on placebo.[1]

Adverse Reactions

Sildenafil has been administered to more than 3,700 patients during clinical trials; over 550 patients have been treated for over one year.[1] The rate of discontinuation due to adverse reactions was not significantly different for sildenafil from that for placebo (2.5% *vs* 2.3% respectively).[1] The most common side effects reported with treatment included headache, flushing, dyspepsia, nasal congestion, urinary tract infection, visual abnormalities, and diarrhea.[1] Table 1 lists the adverse effects reported by ≥ 2% of patients treated with sildenafil and more frequently with treatment than with placebo.[1] Other adverse reactions which occurred at a rate of ≥ 2% but equally on treatment and placebo included respiratory tract infection, back pain, flu syndrome, and arthralgia.[1] In fixed dose studies, dyspepsia (17%) and abnormal vision (11%) were more common at 100mg than at the lower doses (the corresponding rates with placebo are not provided).[1] No cases of priapism were reported.

An open-label, uncontrolled, flexible-dose study in 317 patients evaluated the tolerability and safety of sildenafil taken as required (not more than once daily) over a period

Table 1.—Adverse events reported by ≥ 2% of patients treated with sildenafil in flexible-dose studies[1]

Adverse event	Percentage of patients reporting event[†]	
	Sildenafil (n=734)	Placebo (n=725)
Headache	16%	4%
Flushing	10%	1%
Dyspepsia	7%	2%
Nasal congestion	4%	2%
Urinary tract infection	3%	2%
Abnormal vision[§]	3%	0%
Diarrhea	3%	1%
Dizziness	2%	1%
Rash	2%	1%

[†] The table includes adverse events reported by ≥ 2% of patients and more frequent on sildenafil than placebo; adverse effects which occurred at a rate of ≥ 2% but equally on treatment and placebo included respiratory tract infection, back pain, flu syndrome, and arthralgia.

[§] Abnormal vision: Mild and transient, predominantly color-tinge to vision, but also increased sensitivity to light or blurred vision. In these studies, one patient discontinued due to abnormal vision.

of one year.[8] Forty patients (12.9%) withdrew from the study due to lack of efficacy (4.2%), adverse effects (3.9%), "cure" of erectile dysfunction (1.3%),and other (1.6%). Six patients (1.9%) were lost to follow-up. The incidence and types of adverse effects reported were consistent with other studies (see Table 1).

Single oral doses of sildenafil produced no "clinically relevant" electrocardiogram changes in normal volunteers.[1] In healthy volunteers, single oral doses of sildenafil produced a decrease in blood pressure of about 10mm Hg (systolic or diastolic not specified).[1] Patients with ischemic heart disease who received 40mg sildenafil intravenously had similar reductions in blood pressure.[1] The hypotensive effects of sildenafil may be related to PDE5 in vascular smooth muscle.[1] "Larger but similarly transient" effects on blood pressure were noted in patients taking concomitant nitrates; therefore, the administration of sildenafil is contraindicated in these patients.[1] When sildenafil was coadministered with amlodipine in hypertensive patients, the mean additional reduction in systolic blood pressure was 8 mmHg (diastolic, 7 mmHg).[1]

"A comprehensive battery of visual function tests" was conducted at doses up to twice the maximum recommended dose.[1] "Mild, transient, dose-related impairment of color discrimination (blue/green) was detected," with peak effects occurring near the time of peak plasma levels.[1] This effect is consistent with inhibition of PDE 6, which is involved in phototransduction in the retina. In flexible titration studies of four to 26 weeks duration, 3% of patients on sildenafil reported visual disturbances, compared to no such findings in placebo-treated patients.[1] In fixed-dose studies, the incidence of visual abnormalities was somewhat higher (11%).[1]

Drug Interactions

Since sildenafil is metabolized principally by the CYP3A4 and 2C9 isoenzymes, concomitant administration of inhibitors or inducers of these isoenzymes may be expected to cause increases or decreases in plasma concentrations of sildenafil. *In vivo* studies demonstrated significant increases in sildenafil area under the curve (AUC) when sildenafil was administered with cimetidine (a nonspecific CYP450 inhibitor) and erythromycin (a specific CYP3A4 inhibitor) (see Table 2).[1] Pharmacokinetic data from clinical trials showed no significant drug interactions when sildenafil was coadministered with CYP2C9 inhibitors (such as warfarin) or CYP2D6 inhibitors (such as SSRIs, TCAs).[1]

Administration and Dosage

For most patients, the initial recommended dose is 50 mg taken, as needed, approximately one hour before sexual activity.[1] However, sildenafil can be taken from four hours to one half hour before sexual activity.[1] The dose may be increased to 100mg or decreased to 25mg based on efficacy and tolerability. The maximum recommended dosing frequency is once per day.[1]

Factors which are associated with increased plasma levels of sildenafil include advanced age, hepatic or renal impairment, and concomitant administration of CYP450 inhibitors (Table 2).[1] Since higher plasma levels may increase both efficacy and adverse effects, a lower starting dose of 25mg should be considered in these patients.[1]

Table 2.—Factors which are associated with increased plasma levels of sildenafil[1]

Factor	Percent increase in AUC
Age >65 years	40%
Hepatic impairment (eg, cirrhosis)	80%
Severe renal impairment (CrCl < 30 mL/min)	100%
Concomitant use of cimetidine (non-specific CYP450 inhibitor)	56%
Concomitant use of potent CYP450 inhibitors (erythromycin, ketoconazole, itraconazole, mibefradil)	200%

Sildenafil potentiates the hypotensive effects of nitrates; the use of sildenafil in patients who are concurrently using nitrates in any form is contraindicated.[11] Sildenafil has not been studied in patients who are using other therapies for erectile dysfunction concomitantly.

Cost

Average wholesale price for Viagra™: $6.88 per tablet (all strengths, 25 mg, 50 mg,100 mg).[9]

Place in Therapy

Sildenafil is an important addition to the available therapeutic modalities for the treatment of erectile dysfunction. Although the diagnosis and treatment of erectile dysfunction have improved in recent years, current treatments are suboptimal for many patients due to lack of efficacy or adverse effects.[2,10] Sildenafil is the only as-needed oral therapy currently approved by the FDA. Although sildenafil does not "cure" erectile dysfunction in all patients, it provides a unique alternative to the available treatment options. Since a relatively small number of patients has been treated for greater than one year, caution is warranted until further long-term safety data become available as the drug is widely used in the general patient population. Sildenafil has not been shown to enhance sexual function in men with normal erectile function.

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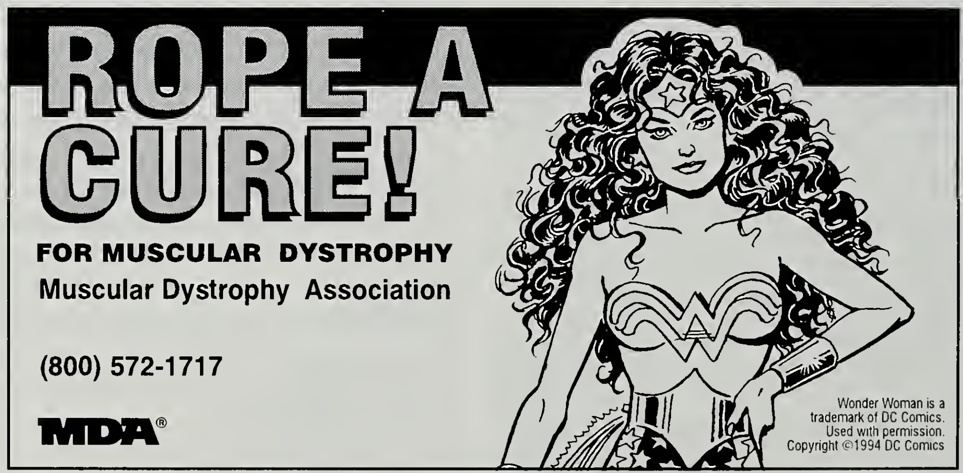

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Assessing Adolescent Pregnancy—Maine, 1980–1996

DESPITE prevention efforts at the state and federal levels, adolescent pregnancy rates in the United States are among the highest in developed countries.[1] The 1996 Personal Responsibility and Work Opportunity Reconciliation Act* mandates a national strategy to prevent pregnancy among teenagers and requires that states establish goals to reduce the incidence of "out-of-wedlock" pregnancies, particularly among teenagers. Adolescent pregnancy and birth rates are declining across the nation;[2] in particular, the rates have decreased substantially in Maine.[2] This report summarizes an evaluation of pregnancy rates for persons aged 15 to 19 years in Maine and an assessment of clinical and behavioral factors that may have contributed to decreasing rates during 1980–1996 by the Maine Department of Human Services, Bureau of Health (MBH); the Family Planning Association of Maine (FPA); and CDC. From 1980 through 1996, pregnancy rates in Maine among females aged 15 to 19 years decreased from 67.9 to 45.6 pregnancies per 1,000. A decrease in oral contraceptive (OC) use and increases in the use of condoms and long-acting methods were significantly correlated with the decrease in adolescent pregnancy rates from 1984 to 1996.

Maine vital statistics data for 1980-1996 were used to assess adolescent pregnancies, births, and abortions by age, marital status, education, partner's age, and previous pregnancies. Annual reports from FPA, the only recipient of Title X† funds in Maine and the largest provider of reproductive health-care services in the state, were used to examine clinical factors that may have contributed to decreasing adolescent pregnancy rates (eg, what contraceptive methods clients reported using). The Maine Pregnancy Risk Assessment Monitoring System (PRAMS), a survey of new mothers about pregnancy behaviors, practices, and outcomes, was used to determine the number and rate of unintended pregnancies among adolescents who gave birth. Chlamydia rates from the MBH Sexually Transmitted Diseases Surveillance System were used as a proxy indicator to help evaluate trends in unprotected intercourse among adolescents. The Maine Youth Risk Factor Behavior Survey, a survey of adolescents in grades 9 to 12, was used to obtain information about adolescent sexual behavior. Data from the Maine Department of Education were used to assess high school dropout rates and the percentage of high school seniors who intended to pursue postsecondary education.

Adolescent pregnancy rates were calculated as the total reported live-born infants, abortions, and fetal deaths per 1,000 females in Maine for females aged 15–17, 18–19, and 15–19 years;[3] fetal losses at <20 weeks' gestation were not included. Population data are from the MBH, Office of Data, Research and Vital Statistics. Trends in adolescent pregnancy, birth, and abortion rates were tabulated by demographic variables, and changes in potential explanatory variables were examined over time. Correlation coefficients (r) and *P* values were used to assess the strength and significance of correlations between these factors and adolescent pregnancy rates.

From 1980 through 1996, pregnancy rates in Maine among females aged 15–19 years decreased from 67.9 to 45.6 pregnancies per 1,000; the largest decrease occurred from 1991 to 1992 (Table 1, Fig. 1). Both birth and abortion rates decreased among females aged 15–17 and 18–19 years. Among females aged 15–19 years, the percentage of pregnancies among those who were unmarried increased from 58% to 83%, while the percentage of pregnancies among those with a previous pregnancy decreased from 29% to 24%. There were no substantial changes in mean years of education or partner's age among adolescents who became pregnant.

From 1984 through 1996, the percentage of females aged 15–19 years who were seen at FPA clinics was approximately 22% per year (Table 1). Oral contraceptives have been the predominant family planning method of adolescents at the FPA clinics, but the percentage using OCs declined from 75% to 58%. Condom use increased from 5% to 14%, and the use of long-acting contraceptive

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*Public Law 100193.

†Title X provides federal grants for family planning services to adolescents and low-income women.

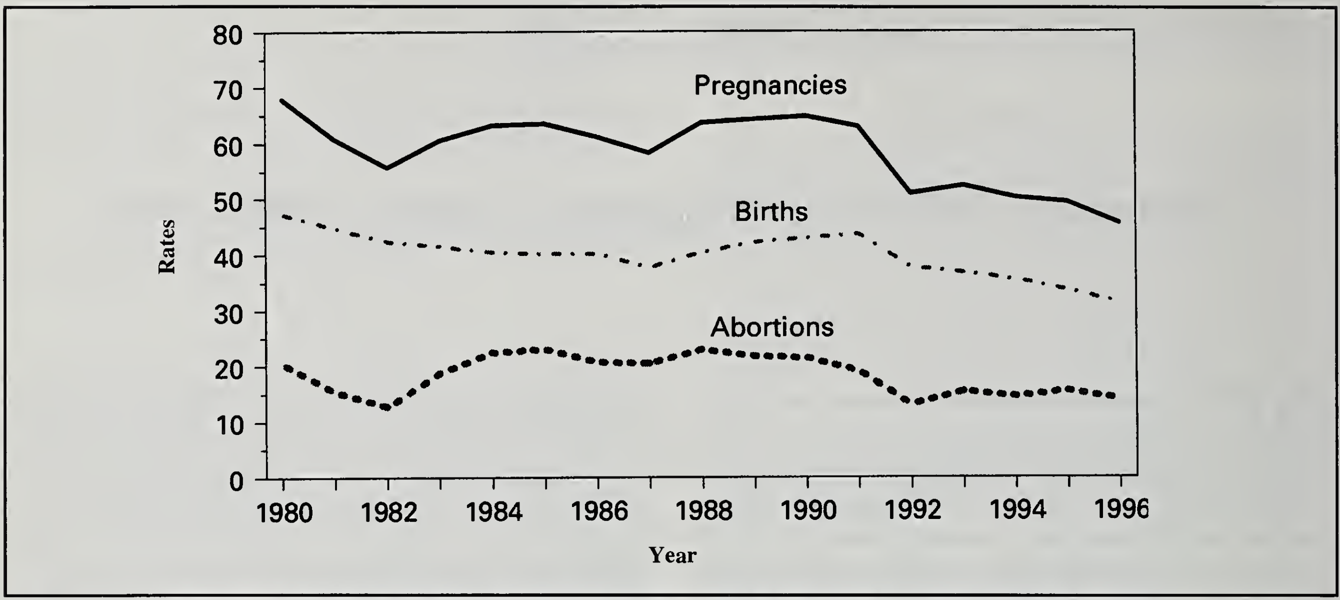

Figure 1.—Pregnancy, birth, and abortion rates per 1,000 females aged 15–19 years—Maine, 1980–1996.

methods (primarily Norplant®§ [Wyeth-Ayerst, Philadelphia, Pennsylvania] and Depo-Provera® [The Upjohn Company, Kalamazoo, Michigan]) increased from <1 % to 11%. Both the decrease in OC use and the increase in use of condoms and long-acting contraceptive methods among FPA clients were significantly correlated with the decrease in adolescent pregnancy rates from 1984 to 1996 (r=0.76, –.85, and –0.77, respectively).

Changes in some behavioral factors also were significantly correlated with the decrease in adolescent pregnancy rates. From 1988 to 1996, rates for chlamydia among females aged 15–19 years (a proxy for having unprotected intercourse) decreased from 27 to eight cases per 1,000 (correlation with decrease in adolescent pregnancy rates: r=0.96). From 1989 to 1996, unintended pregnancies among adolescent females who gave birth increased from 65% to 77% (correlation with decrease in adolescent pregnancy rates: r=4.77). Among males and females, from 1980 to 1996, the high school dropout rate decreased from 4% to 3% (correlation with decrease in adolescent pregnancy rates: r=0.74), and the percentage of high school seniors who indicated a goal to pursue postsecondary education increased from 45% to 62% (correlation with decrease in adolescent pregnancy rates: r=-0.57). The percentage of males and females aged 15-19 years who had ever had sexual intercourse was 58% in 1991, 49% in 1995, and 52% in 1997; the changes in these percentages were not statistically significant.

Reported by: E. Kieltyka, Family Planning Association of Maine, Augusta; J. Foster, F. Antonicci Maine Department of Education; F. Wolman, M.D., D. Hall, M.N., B. Corkom, D.A. Mills, M.D., Bureau of Health, Maine Department of Human Services Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; Division of Health Promotion Statistics, National Center for Health Statistics; Division of Applied Public Health and Training (proposed), Epidemiology Program Office; and an EIS Officer, CDC.

Editorial Note: A thorough assessment of factors influencing adolescent pregnancy rates at the state level can be used to target adolescent pregnancy prevention efforts and evaluate progress toward national health objectives for 2000. This retrospective assessment of pregnancy rates among adolescents in Maine illustrates how states can identify trends in adolescent pregnancy rates and associated factors. In Maine, changes in behavioral factors may have had the greatest impact on adolescent pregnancy rates, including increased condom use, decreased high school dropout rates, and increased intent to pursue postsecondary education. The use of long-acting contraceptive methods was rare before 1993 and therefore could not have contributed to the large decrease in adolescent pregnancy rates from 1991 to 1992. Decreases in rates for chlamydia may indicate a decrease in the incidence of unprotected intercourse among this group.

This report is subject to at least five limitations. First, a critical factor that could not be assessed adequately was the school health education program in Maine. However, the 1996 Maine School Health Education Profile indicates that 97% of public middle schools and senior high schools require education about human immunodeficiency virus;

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§Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

of those schools, 85% taught condom efficacy and 62% taught correct use of condoms (J. Foster, Maine Department of Education, personal communication, 1998). Second, individual characteristics or behaviors could not be connected to the outcome of adolescent pregnancy and persons could not be followed over time. Third, data were incomplete for some factors that were examined and lacking for other potentially important determinants (eg, patterns of care and visits at family-planning clinics and qualitative data about attitudes of adolescents over time). Fourth, most of the data had not been computerized, which limited analytic possibilities. Finally, changes in reporting practices over time could account for the change in pregnancy rates among adolescents; however, there were no obvious changes in reporting practices during 1980-1996 (Maine Vital Statistics Office, personal communication, 1998).

As a result of the findings in this report, the collaborating agencies have recommended the development of a prospective system to monitor and assess adolescent pregnancy rates and potential determinants of risk for pregnancy among adolescents. The Maine Adolescent Pregnancy Assessment Team would be a collaboration between agencies that collect data and agencies that use the data in

Table 1.—Pregnancy rates* and potential determinants of pregnancy among adolescents, by percentage or rate, and correlations between the potential determinants and adolescent pregnancy rates—Maine, 1980–1996

	Females aged 15–19 years								Males and females in high school	
			% of FPA[†] clients reporting primary contraceptive method				Births unintended at conception			
Year	Pregnancy rate	% Who were FPA clients	OCs[§]	Condoms	Long-acting methods[¶]	Chlamydia rates	%	(95% CI**)	% High school dropouts	% High school seniors with intent to pursue post-secondary education
1980	67.9								4.2%	44.8%
1981	60.7								3.9%	45.9%
1982	55.7								3.6%	45.7%
1983	60.5								3.6%	47.7%
1984	63.2	21.8%	75.4%	5.2%	0.4%				3.6%	51.1%
1985	63.5	22.5%	78.0%	4.5%	0.3%				3.5%	53.6%
1986	61.1	23.6%	81.0%	3.8%	0.2%				3.5%	56.3%
1987	58.3	24.1%	82.4%	4.1%	0.1%				3.8%	56.6%
1988	63.6	22.2%	81.8%	5.3%	0.1%	27.4			4.0%	56.7%
1989	64.2	23.3%	80.0%	5.9%	0.1%	30.4	65.0%	(54.6%-75.3%)	3.7%	53.6%
1990	64.7	23.8%	78.4%	6.7%	0.0%	29.8	70.7%	(60.2%-81.3%)	3.3%	54.7%
1991	62.9	23.7%	77.9%	6.9%	0.1%	21.4	60.5%	(49.7%-71.3%)	3.0%	56.6%
1992	50.9	21.7%	78.3%	7.5%	0.3%	15.7	80.5%	(69.3%-91.8%)	2.9%	56.4%
1993	52.3	22.2%	74.4%	9.7%	1.2%	13.0	76.4%	(65.5%-87.3%)	2.7%	57.8%
1994	50.2	21.7%	68.7%	10.8%	4.4%	10.3	72.1%	(60.0%-83.9%)	2.9%	58.4%
1995	49.3	26.0%	55.1%	12.0%	10.1%	10.8	85.2%	(75.8%-94.5%)	3.0%	59.4%
1996	45.6	23.9%	58.5%	14.1%	11.2%	7.5	76.5%	(65.8%-87.2%)	2.9%	62.1%
Correlation with adolescent pregnancy rates (r)		–0.12	0.76[††]	–0.85[††]	–0.77[††]	0.96[††]	–0.77[††]		0.74[††]	–0.57[††]

*Per 1,000 female population aged 15–19 years.

†Family Planning Association of Maine.

§Oral contraceptives.

¶Eg, Norplant® (Wyeth-Ayerst, Philadelphia, Pennsylvania) and Depo-Provera® (The Upjohn Company, Kalamazoo, Michigan). Use of trade names and commercial sources is for identification only and does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

**Confidence interval

††P<0.05.

making decisions on policies and programs (eg, FPA; state departments of human services, education, and labor; and other state, professional, and community-based organizations). Changes in existing data availability and evaluation (providing adequate confidentiality) would need to facilitate 1) access to data about persons to allow follow-up over time, 2) examination of data by relevant geographic areas (eg, county, school district, or community), 3) the linking of vital statistics and family planning clinic data to adolescents' clinic experience and pregnancy status, and 4) access to additional relevant data sources (eg, the Maine School Health Education Profile). The information would enable policy makers and program planners to develop plans for adolescent pregnancy prevention efforts. Other states may want to consider using a similar prospective assessment of adolescent pregnancy rates and potential determinants to better guide research and prevention efforts at the state level.

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Neil J. Grey, M.D.
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THE MEDICAL LETTER

A New Rabies Vaccine

RabAvert (Chiron), a new human rabies vaccine prepared in purified chick embryo cell culture (PCEC), has been marketed in the USA for pre- and post-exposure prophylaxis. It is available in other countries as *Rabipur.* Human rabies is rare in the United States, but thousands of people receive post-exposure prophylaxis every year (Noah DL, et al, *Ann Intern Med*, 128:922, 1 June 1998).

Rabies Vaccines in the U.S.A.

Vaccine	**Cell culture**	**Cost***
HDCV *(Imovax)* Pasteur Merieux Connaught	Human diploid cells	$727.50
RVA (Rabies Vaccine Adsorbed) - SmithKline Beecham	Fetal rhesus diploid lung cells	655.50
PCEC *(RabAver2)*- Chiron	Chick embryo	687.50

*Cost to the pharmacist for the five doses recommended for post-exposure prophylaxis, according to wholesale price (AWP) listings in Drug *Topics Red Book 1998.* It does not include the use of rabies immune globulin, which for a 70-kg patient adds about $700 more.

FORMULATIONS—All rabies vaccines available for human use in the U.S.A. are prepared in cell culture and are much safer than rabies vaccines prepared from infected animal brains, which are still used in some developing countries. The widely used HDCV vaccine has, however, been associated with a 6% incidence of serum-sickness-like (type III) hypersensitivity reactions to booster doses given months or years after the primary series (Fishbein DB, et al, *Vaccine* 1993; 11:1390).

POST-EXPOSURE PROPHYLAXIS—After suspected rabies exposure, the wound should be washed with soap and water, and human rabies immune globulin *(Imogam Rabies-HT; BayRab)* should be given in a dose of 20 IU/kg, with as much of the dose as possible infiltrated at the site of the wound and the rest given IM at a site distant from the vaccine injection. At the same time, a 1-mL dose of rabies vaccine (HDCV, RVA, or PCEC) should be given IM in the deltoid (or the anterolateral thigh in children) and repeated on days three, seven, 14, and 28 after the first dose. Persons who were previously immunized with a cell-culture vaccine or who have a documented antibody response to other rabies vaccines do not need rabies immune globulin and should receive only two doses of rabies vaccine on days zero and three. The PCEC vaccine appears to be as effective as HDCV; it has been 100% effective in preventing rabies in patients with severe exposures (Dreesen DW, *Vaccine* 1997; 15 suppl:S2).

PRE-EXPOSURE PROPHYLAXIS—People at high risk of being exposed to rabies virus, such as veterinarians, animal control and wildlife professionals, personnel in laboratories that work with the virus, and adventure travelers going to rabies-endemic areas should receive three 1-mL injections of rabies vaccine IM in the deltoid on days zero, seven, and then either 21 or 28. Only the HDCV vaccine has been shown to be effective (in a dose of 0.1 mL) when given intradermally. Those with frequent risk of exposure should have their antibody titer checked or receive a booster dose every two years. Antibody responses with the PCEC vaccine are similar to those with the HDCV vaccine.

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INTERCHANGEABILITY—Changing from one rabies vaccine to another during a pre- or post-exposure series is not recommended because of a lack of data on the effectiveness of such a practice. However, use of PCEC as a booster has invariably produced a marked anamnestic response in antibody titers when HDCV was used for primary vaccination.

DRUG INTERACTIONS—Antimalarial drugs, corticosteroids, and other immunosuppressive drugs may interfere with the antibody response to rabies vaccines.

ADVERSE EFFECTS—As with HDCV and RVA, mild erythema, swelling and pain can occur at the site after injection of the PCEC vaccine. Serum-sickness-like (type III) hypersensitivity reactions like those associated with booster doses of HDCV have not been reported with PCEC. As with the other vaccines, anaphylaxis and severe neurological symptoms temporally associated with administration of the new vaccine have been reported rarely. Severe egg allergy is a contraindication to use of the PCEC vaccine.

CONCLUSION—The new rabies vaccine *(RabAvert)* prepared in purified chick embryo cell culture appears to be as effective as previously available rabies vaccines, without causing the serum-sickness-like hypersensitivity reactions sometimes seen with booster doses of the HDCV vaccine.

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Is Telemedicine Justifiable?

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ABSTRACT—A three-year experience in urban telemedicine is presented. The digital technology linking a community teaching hospital to a nearby clinic is described, as is the typical protocol for the consultations. The medical advantages and disadvantages, the security implications, and the cost-effectiveness of this project are analyzed.

Introduction

TELEMEDICINE has been increasingly recognized as a valuable tool in medical practice.[1–3] The explosion of this topic in the literature and the media is fueled by the enthusiasm shown by physicians, government agencies, academic medical centers, research centers, industry, and the military.[4–7]

The Beulah Hinds Center at Norwalk Hospital, initiated the I-SNET Pilot Telemedicine Service (PTS), in affiliation with AmeriCares and Southern New England Telephone Company (SNET) in November 1994.

Abbreviations Used in Text

NTSC = National Television Standards Committee
JPEG = Joint Photographic Expert Group
ISDN = Integrated Services Digital Network
POTS = plain old telephone service

The Norwalk Hospital is a community hospital serving a quarter of a million people in southwest Connecticut. It is a multispeciality teaching facility and is affiliated with the Yale University School of Medicine.

AmeriCares, a world-wide relief organization, opened its first primary-care clinic in the United States in South Norwalk, in November 1994. The AmeriCares Free Clinic is a primary- care clinic for the uninsured and underinsured. It is staffed by volunteers including physicians, nurses, and others. There is no charge to the patient.

SNET, a local telephone company headquartered in New Haven, donated all of the telemedicine equipment and the dedicated lines. They continue to provide service as part of the information superhighway initiative in the state of Connecticut.

In this paper we present our experience in evaluating the potential and in seeking justification for the role of telemedicine consultations in the practice of primary health care.

The objective of this project is to supply telemedicine consultations and education from hospital specialists to clinicians and patients at the primary-care clinic. This paper describes our experience in attempting to carry out this objective.

The Technology

The Pilot Telemedicine Service is facilitated by two telemedicine workstations: one at Norwalk Hospital (consultant site) and the other at the AmeriCares clinic in South Norwalk (examination site). This system supports real-time, *full-motion* videoconferencing between the specialist at the hospital and the clinician and the patient at the clinic. Full-motion video enhances physician and patient acceptability of telemedicine as a tool to provide real-time, personal interactions. Our system supports this video

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communication with real-time audio and integrates a set of clinical probes at a total transmission rate of 1.4 x 5 megabytes per second (Mbps). The three types of information, video, audio, and data, are transmitted individually through dedicated lines. The availability of large bandwidth for transmission ensures faithful transfer of clinical expertise, thereby enhancing the clinical acceptance of our telemedicine system.

The two workstations are not identical; each is tailored to the needs of its own site. Avoiding unnecessary duplication of equipment reduces total cost. The platform at both sites is Sun Microsystem's Sparc-20 (Model 50) UNIX workstation with 64 MB of RAM and two 1.05 gigabyte hard disks. The operating system is Sun's Solaris 1.1.1 version B UNIX. The 20" color console has 1152 by 900 lines of resolution and 30 foot-lambert brightness. The hardware can support bi-directional, live-network video at 30 frames per second (320x240) of NTSC video images. Since the video complies with the NTSC standard, other video modalities, such as otoscopes and ophthalmoscopes, are readily transmittable. A video switch box controls the video source input to the workstation. A color copier located at the clinic can be operated from both sides and will make a hard copy of the video.

Software tools are controlled from a single-tool window manager. Each tool is a stand-alone module and thus can be enhanced when technology changes. The tools are written in C, C++, and UNIX script files, and run on a 24-bit X11R4 server under the Openlook window. There is a roentgenogram viewing tool to view digitized x-rays that are primarily 8-bit TIFF files; the acuity can be adjusted by the digitizer controls. Live NTSC video source is digitized and transmitted in real time in one of three sizes: full (640X480), CIF (320X240), or QCIF (160X120). The JPEG microchip onboard the 24-bit frame buffer compresses the outgoing 24-bit video frames to a user-specified quality rating. JPEG is unique among compression algorithms in that it maintains a constant *quality* rather than a constant *compression ratio*; and the compression ratio varies depending on the scene content. A white-board tool provides a common, shared drawing and viewing window between the consultants as both sides see the same data.

Implementation and Experience

The primary-care physician initially requests a telemedicine consultation during the patient's visit. The clinic nurse then informs the hospital telemedicine physician coordinator. The urgency of the consultation and the availability of the specialist are discussed. If the specialist is immediately available, the consultation is conducted. Otherwise, if the problem can wait, the appointment is scheduled at a mutually convenient time.

The nature of the patient's problem determines the process, the specialist, and the instruments needed to conduct the consultation. X-ray films can be scanned to the clinic for common viewing and discussion. Electrocardiograms can be displayed. An electronic, remote stethoscope can allow the consultant at the hospital to listen to the heart sounds of a patient at the clinic in real time. The zoom lens of the clinic camera can be used to view skin lesions and observe closer examinations.

After initially planning that this pilot project be used primarily for specialty consultations, we found a further use for telemedicine: three months into the project, the clinic's need for patient education added another dimension to our telemedicine consultations.

Some types of consultation are as follows:

- *Dermatology.*—The dermatologist identifies certain features of a skin condition with the aid of the zoom lens on the clinic camera, leading to the diagnosis and proper treatment.
- *Cardiology.*—The cardiologist interviews the patient (observing body language), listens to the heart by the remote stethoscope, and views the scanned EKG and the chest film.
- *Neurology.*—The neurologist examines a patient remotely, observes the patient walking, directs the clinic nurse to test the reflexes, and makes a diagnosis.
- *Diabetes education.*—The diabetic nurse-clinician assesses the level of the patient's understanding of the disease and individualizes the education as needed. The clinician observes their technique in glucometer use and insulin administration, and makes corrections when indicated.
- *Nutrition education.*—The hospital nutritionist reviews the patient's medical and dietary histories. The patient is educated about eating habits and calories, with the help of realistic plastic models of food. Following the education encounter, an individualized diet is designed and mailed to the patient.

A typical subspecialty consultation is that of a 53-year-old female with abdominal pain, anemia, and weight loss. She had been seen initially by the clinic physician who diagnosed pernicious anemia and hyperthyroidism. Because of persistent abdominal pain, a gastroenterology consultation was requested. The specialist observed and listened as the patient described her pain and other symptoms. The specialist noted that her diagnoses and a positive antinuclear antibody suggested possible malabsorption. The fact that they were able to interact, physician to physician, clarifying the complex problem, and questioning the patient together, as if they were in the same room, demonstrates the invaluable features of a telemedicine consultation.

A typical patient education session is that of a 34- year-old male with insulin-dependent diabetes mellitus (IDDM). Because of a poorly controlled IDDM, resulting in hypoglycemic episodes, a consultation with a diabetes nurse clinician was obtained. The clinician reviewed the patient's history and questioned him about his eating habits and insulin dosage. She then observed his technique in drawing and preparing his insulin injection and the site of administration. From this information, she ascertained that he was not taking the prescribed dosage and was able to correct his technique. He returned in two weeks with his blood sugar diary and glucometer so that his new technique could be observed via telemedicine.

Although free to the patient and the clinic, the average value of service of the subspecialty consultations was $266, ranging from $95 to $348. The value of service of the patient education sessions was consistently $75. [This is the cost of the consultations that would be expected in our area; and is used by the AmeriCares free clinic to estimate the value of the services they provide. There is no actual cost since the physicians and other health care professionals are volunteers.]

Discussion

Is a telemedicine subspecialty consultation as good as the old-fashioned, in-person kind? The answer is a qualified yes, within reason.

In this setting, we found several clinical advantages of telemedicine. 1) The dynamic exchange between the clinic-based physician, the specialist, and the patient facilitates comprehensive evaluation and immediate treatment. This rarely happens in today's era of medical practice. 2) Patient convenience is certainly another advantage of telemedicine—the patient feels comfortable going to a familiar clinic, a one-stop medical center, if you will. 3) In our clinic, the uninsured and the underinsured patients are the working poor and often have difficulty in obtaining transportation and child care, and cannot afford the loss of wages. These factors may interfere in keeping a scheduled appointment at a specialist's office. 4) The clinic and the hospital medical center are virtually connected via telemedicine. This is not only convenient and beneficial to the patient, but is valuable to the clinic personnel who have access to sophisticated medical decision making and educational help. 5) The timeliness of the consultations is also important. Spot consultations would be ideal, however, even scheduled consultations when specialists are making rounds in the hospital may speed up the process. A telemedicine consultation at the local clinic cuts through these barriers insuring a more timely consultation which could avoid costly visits to the hospital emergency department or even admission to the hospital. 6) Another advantage is the ability to make a color, hard copy of the encounter for the record. For example, a skin problem was viewed and followed for changes at a subsequent visit. In another of our clinic visits, in addition to the record copy, the patient was given a copy of her chest x-ray film abnormality for future reference.

Although many benefits of telemedicine were identified during this experience, a number of disadvantages were also recognized. We did find that the ophthalmoscope was difficult to use; for the most part this was because we do not dilate pupils in our clinic. Ironically, we did use the ophthalmoscope successfully (as a capillaroscope) to check the nail-bed of a patient with scleroderma. In general, a diagnosis which depends on visual data, such as skin, x-ray films, and pathology slides, is more suitable than conditions requiring "hands on" techniques (eg, palpating a mass).

The problem of cost-effectiveness is of importance and must be addressed. The AmeriCares Free Clinic is a primary-care clinic free of charge to the patient and staffed by volunteer doctors and nurses. The equipment and the dedicated lines were donated to the clinic, and therefore the cost-effectiveness must be based on an estimate of its "real world" cost. Remembering that the equipment is state-of-the-art with full motion audio and video, the cost today would be $150,000 for the hardware, $3,250 for the installation of five T1 lines, and $2,000 per month fee for the use of the lines. The use of these lines for three years would be approximately $72,000.

The value associated with telemedicine consultations during this period, including transportation, time wasted with loss of paying and including the possible savings from the avoidance of emergency visits, would come to no more than $15,000.

This figure, however, must be viewed in light of the fact that the free clinic was open six hours per week for the first year, and subsequently 12 hours per week. In no way would this generate the work of a network of clinics connected to a medical center or a managed-care facility. In addition, past experience tells us that the cost of the hardware will become less with time. By changing to other types of communication lines, the user would pay per use rather than a straight fee. This would decrease the monthly cost.

The expanded use of the equipment to administration and continuing medical education would further its cost-effectiveness.

Telemedicine and security of medical records and protection of patient confidentiality is of paramount importance. This may be achieved through limited access and passwords.

In our consultations we have a dedicated line from the hospital to the clinic, and, at the moment, we keep no records in our system. After the consultation we take a color print of the encounter mainly to show important findings such as skin lesions and x-ray film images that would be useful to review at a later date. The consultation is verbal followed by a written consultation which is then mailed to the clinic. If we decide to add, store, and forward to our system, the protocol will have to change.

A discussion of telemedicine is not complete without addressing the problems that must be faced in the real world.

1. *Third party reimbursement.*—Most insurance companies do not reimburse for telemedicine, with some exceptions for telepathology and teleradiology. Medicare in January 1999 will reimburse for rural areas that the government has designated as having a shortage of health-care professionals.[8]
2. *Medical licensing issues.*—Licensing out-of-state physicians must be addressed state by state. Connecticut law requires that out-of-state physicians be licensed in Connecticut if consulting on an ongoing contractual basis. However, an out-of-state physician does not need a Connecticut license if he consults with a Connecticut licensed physician on an irregular basis, or consults with a medical school on an educational or training basis.[9]
3. *Quality of care issues.*—Quality of care at the present time is in keeping with the common office practice of relying on implicit criteria. Namely, the personal judgment and the prudent practice of appropriate care by the primary-care physician and the consulting health-care provider. In our telemedicine project a review of outcomes was carried out, as was previously described.

   The Joint Commission on Accreditation of Health Care Organizations states that a telemedicine consultation is appropriate care as long as the referring primary-care physician at the patient site writes the orders on the patient's chart.[8]
4. *Medical liability issues.*—It would be prudent to check with one's insurance carrier to be sure that there are no exclusionary clauses. Our clinic requires that our patients sign an informed consent.
5. *Security and patient confidentiality.*—This is assured in our project because we have dedicated lines and the data are kept only in the patient's chart. However, as we switch to Intergrated Services Digital Network (ISDN) lines, and especially the Internet, a software "firewall" will be needed. This will consist of encrypting, message authentication, personal ID, and user identification.[8]

The Post-pilot Phase

The pilot phase has taught us that we cannot justify the cost of five dedicated T1 lines for our free clinic. Furthermore, we may not be able to rely on the continuing generosity of the Southern New England Telephone Company. The following is our experience with other bandwidths:

1. The present equipment was used with two T1 lines and was quite satisfactory for our clinic consultations. The video was reduced to 15 frames per second [instead of 30 frames]. We were able to use our stethoscope, otoscope, white board, and scan our x-ray films. The cost would still be $600 to $800 per month. Unfortunately our equipment will not operate on anything less than two T1 lines.
2. We were recently involved in a telemedicine consultation to Geneva, Switzerland, via an ISDN line, using less expensive equipment. The video was 10 to 12 frames per second and the audio was good. The laboratory results and the recorded history were clear, as were the ECG and x-ray films sent by document camera. The transmission of the coronary angiogram and the echocardiogram was remarkable. The cost of the ISDN line is $50 per month, and one cent per minute. This would definitely be more acceptable for our clinic.
3. A telemedicine consultation was also done on even less sophisticated equipment via a "plain old telephone service" [POTS] to Philadelphia. We have not had enough experience with POTS line telemedicine to make a final judgement.

Conclusion

This initial experience in real-time telemedicine—including specialty consultations and patient education—was rewarding and acceptable to both the patient and the health-care provider.

The future use of this modality to include continuing medical education and administrative teleconferencing, together with the improving technology and the expected reduction in cost, has led us to conclude that telemedicine is indeed justifiable.

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Commentary

COURAGE—An Epistle to a Colleague

Dear Jeremy: In your recent letter to me you asked: "What do we do to protect our residents and residency programs, and ourselves as the teachers?" The answers to this problem are complex. But clearly we must start with some basic physician behavioral modifications if we are to secure any protection for medical education in this country at all, to say nothing about protection of our patients rights!

The first change to be made is the hardest. We must abandon an attitude that is prevalent in some of our medical leadership organizations and in many individual physicians. I refer to the posture that says "to get along you go along." Instead of playing along with the "managed care" scheme, we must expose it for what it is—an economic model and not a medical model. An economic model that can be exceedingly harmful in individual circumstances and devastating to individual patients. Managed care must be actively and effectively opposed by each and every teaching institution, hospital, and individual physician. We have forgotten, or perhaps we have chosen to ignore, the fact that medicine cannot be practiced without doctors. When a managed-care firm throws a contract at you, your hospital, or your academic institution, don't just sign on the dotted line while meekly mumbling "otherwise I'll be left out." Just say NO! Managed care needs doctors and hospitals, but we don't necessarily need them! This is still true now, but it may no longer be true in a few years if certain institutions continue to cut "sweetheart deals" with MCOs. Most of these deals have plenty to do with money, and little or nothing to do with good medical care. For example, Oxford Health Plan recently convinced Columbia P&S in New York to let advanced practice nurses (APRN) function as primary-care providers, replacing physicians in this role. How did they hook a prestigious institution like Columbia into a deal like this? With money, of course. Columbia's faculty practice will be reimbursed for the APRN's services, at least for now, at the same rate that Oxford pays Columbia for doctors visits! Of course, the APRNs are paid less than Columbia's physicians, so Columbia will pocket the difference! This is one example of the "addicting subsidies" that I address later in this letter.

When an MCO offers you a contract, ask them what benefit they bring to your patients, to you, to your institution, and its teaching program if you let them in. Don't just sign on the dotted line because you are panicked over the possibility of losing a few dollars! If you don't let them in, they can't "manage" medicine in your practice, in your institution, or anywhere else! If you don't want them in, the MCO is out! Out of your practice, your hospital, your community—out of your economic web! They need you, not the other way around! Make them pay for the privilege, including the costs of residency training. But be sure that your residency program is adding value to the patients' care. If it isn't, you really should dismantle the program. Most importantly, don't discount yourself for them. Learn this, and practice it faithfully!

Did you notice another of our mistakes which I deliberately let slip by before? We have allowed Newspeak to take over! We are doctors, not "providers." The title doctor connotes a certain level of knowledge, training, and expertise. These qualities are not replaceable with cheaper, quickly trained, and turned out generic substitutes! And those we care for are patients, not "consumers"! We do not get "used up" by our patients! Our language usage determines the boundaries of the debate. Let's start using plain English again, and let us eschew the interchangeable euphemisms created by policy wonks in order to change the ground-rules and compass of the debate!

Next, physicians must relearn the scientific method. Surely, you haven't forgotten this method! A hypothesis is created, controls are put in place, the hypothesis is tested according to the established protocol, and the results noted. The results, if they can be independently duplicated and if they are beneficial, are then followed in future patient care. So- called "evidence-based medicine," "outcomes-based research," and several other "new paradigms" that recently have been created are not scientific method! They are management plans. Costs of care are carefully prefigured into the predetermined "conclusions." The conclusions are based upon group cost-benefit analysis, not individual patient benefit. And the conclusions are not scientific conclusions at all. They are financial goals which become retrospectively justified by the "research." This is goal-based circular reasoning gibberish. You must tell your institutions, and especially your specialty societies, that "evidence-based medicine" is not scientific. It is economic gobbledygook. It is an insult and anathema to the past 500 or more years of scientific progress. And you must let the wanna-be bigshot "professors," who grind out this "research" in return for handsome government payments (called "grants" so that they smell better), know what you think of their "research"! After all, the only people they usually hear from are their equally grant-laden "peer-reviewing" professors, and establishment-cooperating editors of "prestigious journals" that release their latest journals' contents to the lay press prior to publication so that the "hot and sexy findings" are published in newspapers before the physician even receives the journal! These folks have learned that "if it's published in the lay press, it's true." Who are we, mere doctors, to argue with their "scientific method"? Well, we had better start telling them!

And now, there is the hardest job! We must wean our hospitals and academic institutions from their addiction to government funds. When Aneuryn Bevan was asked how he would get the British Medical Association not to speak out against Socialized Medicine in 1947, he said: "I will fill their mouths with gold." We in the U.S. have up to now unfortunately followed our U.K. cousins in this regard, and we are rapidly learning that the "gold" is diminished in amount from that promised. It is fools' gold, and leaves a very bad aftertaste, particularly with regard to the welfare of our patients and the future of graduate medical education in this country.

Lyndon Johnson followed Bevan's principle in 1965 when he declared the existence of a "medical care crisis" because of "too few doctors." He started feeding money to the medical schools. He knew what that free cash inflow would do, and the schools fell for it hook, line, and sinker. When I went to medical school, the department of biochemistry listed six faculty members. Four could teach, the fifth was there for show (a Nobel Prize winner—brilliant, personable, and completely incapable of teaching), and the sixth person was someone whose function I never really could figure out. The last time I thumbed through the school's Bulletin of Information, the biochemistry faculty ran on for eight pages! I am reasonably certain that the medical student population, only 38% larger than when I went to the school, is still being taught biochemistry by four to eight dedicated souls. Many of the other faculty members are there mainly because government money pays for it, it looks impressive in the catalog, and perhaps one of the listed names will turn out to be a "winner" and bring more prestige to the school. The schools could easily do without this. And they could install their own air conditioning and other necessary equipment at the time that they build new research buildings. Instead, they often install air conditioning and research equipment in each lab at later dates, paying for them with funds from the individual laboratory's government research grants! In business, this would be recognized for what it is, gross waste and inefficiency. In business, these sorts of activities would not be tolerated. Effective elimination of these, and other wasteful practices, should be recognized by the schools as constituting effective downsizing. In the end you wind up doing more and achieving more with less. And, in the process, you wean yourself from the excessive cash flow which, in the final analysis, comes out of our excessive taxation. It is something that we have ignored for too long. We must attend to this problem now!

Another example of this sort of waste, and dependency on excessive government funding, was created by the 1983 budget reconciliation act. This measure set up the diagnosis-related groups (DRG) system for paying hospitals by diagnosis rather than by actual cost reimbursement. Time was of the essence when Congress was writing this bill, funds were limited, and teaching hospitals were some 8% short on their budgets in the originally proposed bill. In order to save time and get the bill done, Congress created the "teaching hospital indirect reimbursement item" which amounted to 8% of the bill's projected budget. Even worse, they made this bonanza dependent upon the number of residents a hospital had, paying the hospitals about an additional $170,000 per year per resident. Within a year, hospital administrators were recruiting abroad for residents, because each one that they hired was a walking $170,000 check for the hospital! This is no way to create sensible residency programs! This monstrosity distorts the economics of hospital care, and teaching hospitals have stonewalled this issue for 14 years. It is another example of addiction to excessive cash flow and clearly needs reevaluation and downsizing. Residency programs should exist only so long as they increase the quality and value of care received by the patients. And they should exist only where they can expose the residents to true quality learning situations along with dedicated physician-teachers. The true costs of these programs should be paid for because there is real value added for the additional expense. Anything else is subsidized waste.

We can do all of this. But not if we keep worrying that "the guy down the street will sign up for less and I'll be left out!" That is a defeatist philosophy. The powers that be rely on this attitude and successfully squeeze us every way they can. We must not give in to such tactics! Nor can we allow ourselves to be consigned to despair.

We must see to it that the institutions that purport to represent us, be they general or specialty societies, actually represent the interests of our patients, our teaching programs, and us! Look around, you will notice that many of the "old-guard" medical organizations, and many of our specialty colleges, are actively cooperating with every two-bit politician that pretends to give them half an ear. These groups are busily scrambling willy-nilly to cut out a piece of the pie for the perpetuation of their own bureaucracies! They stopped representing their memberships long ago! Their goal has become preserving and enlarging the place in the sun that their paid officers and staff now occupy, even if this occurs at the expense of the membership and of quality graduate medical education. Therefore, if you don't think your organization represents you, tell them, and get out! Without a constituency they will either change to conform to our desires, or wither on the vine.

Consider joining some of the newer, more activist medical organizations such as the Association of American Physicians and Surgeons (to which I belong), other professional organizations, or even one of the new physician unions, so long as the group truly and fairly represents your views. Be sure that they are willing to speak out forcefully on unpopular issues. Be certain that they will take principled positions on important issues and not involve themselves with politically popular posturing. And you must be willing to speak up too. Be an active member of the group, not just a dues payer! And always make sure that your group advances your patients' interests!

In the final analysis, only by protecting your patients' needs, constantly improving the quality of the residency training in your institution, and keeping your institution on the cutting edge of true medical progress can your own future be made secure!

Courage! Best wishes.

Stephen R. Katz, M.D.

(Dr. Katz is an obstetrician-gynecologist in Fairfield, CT who closed his private practice of 25 years in 1994 because of his ethical discomfort with managed care. He is now a health-care consultant, and the president-elect of the Connecticut State Medical Society.)

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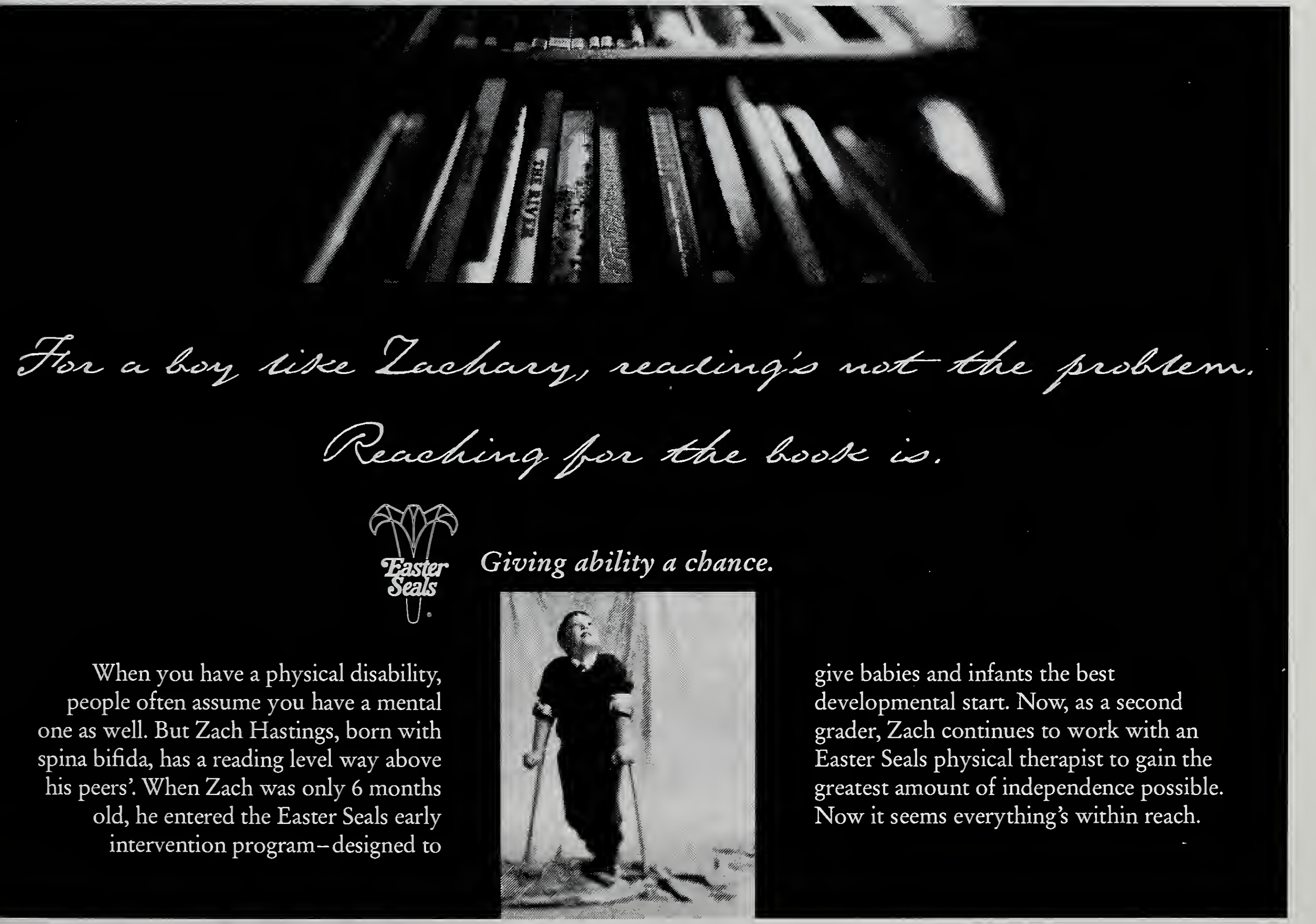
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Medical Care and the Cost of Living

Physicians are interested to know whether the general cost of living has gone up faster or slower than the professional charges by physicians such as an office call. Recently compilations for 1947 were assembled by the Bureau of Medical Economic Research of Chicago using data gathered from 34 large cities by the U.S. Bureau of Labor statistics. The general answer shows that the cost of living for 1947 was higher than the index of any reported medical item. Although the sampling in 34 large cities does not reflect price changes in all places where physicians practice, it does give a picture of what the general trend of prices the American people are paying for their medical care. In a recent release the Director, Dr. F. G. Dickinson states:

"The inescapable conclusion is that the cost of these important items of medical care have risen since 1940, but with the exception of hospital items not as rapidly as the general cost of living. This conclusion reinforces and substantiates the conclusions in my study of the costs of medical care. (*Is Medical Care Expensive?* Bureau of Medical Economic Research, American Medical Association, 1947, twelve pages—breakdowns for 1946 appear in overprinted copies only.) In this earlier study the conclusions were that medical care items as a whole cost the American people $5,600,000,000 in 1946 but that only 3.9 per cent of the total personal consumer expenditures of the American people were spent for these medical care items; this compared with 4.3 per cent in 1940. More particularly, in 1946 the amounts spent for physicians' services and hospitals were 1.0 per cent and 0.6 per cent of total personal consumer expenditures in the year. Hence the general conclusion was that the American people were spending a smaller percentage of the total consumer budget for medical care as a whole and for physicians and hospitals as components thereof. It was also stated that in 1946 physicians received only 26 per cent of all the dollars spent for medical care as compared with 31 per cent in the base period, 1935-39, and 35 per cent in 1929, the first year for which the data were gathered and published by the U.S. Department of Commerce. On the other hand, it was shown that the amount spent for drugs in 1946 had risen to 24 per cent of all dollars spent for medical care as compared with only 21 per cent in the base period, 1935-39, and 20 per cent in 1929. Thus the story of the wonder drugs is written into the recent history of medical economics. On the other hand, the percentages for hospitals were 16, 17, and 13 respectively; for dentists the percentages were 13, 13, and 16. It was also stated in my earlier study that the people are getting more for their money. They get well quicker, they live and earn longer. The type of medical care given in 1946 differs as much from the type given in 1929 as a 1946 passenger automobile differs from a 1929 model. Life expectancy at birth rose from 59 years in 1929 to 67 years in 1947.

"Whether one examines the record of total expenditures of the American people for medical care or the prices of significant items during recent years, he comes to the general conclusion that the American people have been fortunate in that the costs of keeping well have not risen as rapidly as the cost of living. This information and these conclusions should be of great importance to all citizens who are concerned with the general problem of trying to improve the medical care of the American people."

Reprinted from the *Connecticut State Medical Journal*, July 1948.

Editorial: A Corporate Society

The announcement by one of the large labor unions of a plan to establish a medical center to give care to its members is significant because it gives concrete evidence of the growing desire on the part of workers to remedy one of the problems of insecurity which many face. The fear of prolonged or catastrophic illness creates anxiety, just as the fear of loss of work and of the insecurity of old age. Such fear is threatening to personal integrity and engenders loss of self-respect. It is commendable that such groups should seek to remedy such problems within the structure of their own organization, in their own hands, and that they have the wisdom to foresee the hazards of attempts at remedy under government control. The movement, which seeks to interest both Labor and Management, shows signs of great potentiality, for other large organizations are rapidly becoming similarly minded. Medicine should find in this type of planning a sympathetic interest, for it alone can furnish medical care. It seems apparent that many of the differences which exist between Labor and Management today are those which require adjustment along the lines of social welfare. It is in this field that prepayment medical insurance should play an important part. For such insurance to be adequate and satisfactory there is no question that it should be under the control of the medical profession. Furthermore, it must be of such comprehension in coverage and soundness in financial structure as to be an attractive investment. This is a form of "socialized" medicine in which Medicine can take a proper part with honor and without loss of integrity. It should be recognized as an opportunity for Medicine to cooperate with Labor and Management toward the highest good, which is the pubic good. Medicine, like Labor and Management, is not outside of human life but within it. Whether we like it or not we have to realize that we are living in a corporate age and, difficult as it often appears, we are forced to the conclusion that many of the ideas of human relationships which we have always considered as inherent and stable in our civilization are no longer tenable and must be abandoned. The Sage of Concord wrote: "Society is everywhere in conspiracy against its members," but he also wrote in the same essay: "accept the place the divine Providence has found for you, The Society of your contemporaries, the connection of events."

Vagitus Uterinus

To the Editor: The following instance of vagitus uterinus may be of interest to your readers and I am therefore taking this opportunity to briefly outline a case which was under my care recently.

The patient was a 24 year old primigravida at term and in labor. She had a twin pregnancy. The leading fetus presented as an occiput posterior.

When dilation was about 5 cm. the membranes were ruptured. At 8 cm. dilatation low spinal (saddle block) anesthesia was given. One half hour after the block, the cervical dilatation was complete and the patient was moved to the delivery room and prepared for delivery.

Vaginal examination revealed a compound presentation. A hand was presenting with the occiput. On determining this complication the examining hand was withdrawn and the findings were explained to the nurses who were present. As we were discussing the presentation we heard a cry. Then we heard another cry, and the patient exclaimed, "That must be my baby!" A third crying episode then occurred, and this we recognized as arising from within the mother.

Delivery was then effected. The leading twin (the one which cried) needed some aspiration but no resuscitation. The second twin, the membranes of which were intact, needed active resuscitative measures after delivery. These were dizygotic twins.

The reports of vagitus uterinus show it to be a rare occurrence, up until January 1947, only 125 cases being authentically reported. For its production the following conditions are necessary: rupture of the membranes, entrance of air into the birth canal, and stimulation of the fetal respiratory center. This case fulfilled these requirements. The entrance of air into the uterine cavity was apparently facilitated by the compound presentation and the fetal respiration was stimulated by vaginal examination.

Max L. Berlowe, M.D.
New Haven

What Is Your Excuse?

It is an election year in Connecticut. There are gubernatorial, state legislative and U.S. senatorial races. At the same time, the House of Medicine continues under relentless attack in the political arenas. A whole host of paraprofessionals want legislative fiats expanding their scopes of practice. Others want to practice medicine independently without benefit of attending a medical school. At the federal level, the Health Care Financing Administration would love to burden us with onerous documentation guidelines in order that they may even more aggressively pursue us for fraud and abuse.

Who is going to stand up for physicians? The federation of organized medicine will. That is the federation of city, county, and state medical societies together with the American Medical Association. How are we going to advocate for physicians? We will use everything from grassroots campaigns to attending hearings to governmental representatives to professional lobbyists. We will donate to candidates' campaign funds.

Yes, we will make campaign donations. We need the legislators' help with our causes and they need our assistance to be in a position to help us, ie, get elected. This is not an issue of buying votes. There are no votes for sale but, if there were, I would imagine that it would cost a lot more than we have to spend. It is an issue of giving support in hopes of receiving support. This is not a perfect system but it is the only one we have.

The Connecticut Political Action Committee (COMPAC) was started by the CSMS in order to raise funds for use in political campaigns. Each year, the Board of Directors of COMPAC decides which legislators will receive donations and how much they will receive. Both the number and amount are limited by the level of donations to COMPAC. Donations are made to thank those who have helped us in the past and to those who may be reasonably expected to help us in the future.

Look at the successes we have had in Connecticut in the last few years. We have passed a patient protection bill. We have fought off attempts by the APRNs to practice independently. We have stymied the efforts of optometrists to use lasers and the full range of ocular medications. We passed a bill requiring prompt payment of our bills to managed care companies. At the federal level, we persuaded HCFA to put the new E&M codes on hold, indefinitely.

We have done all of this, by the way, with an abysmal participation in COMPAC by the physicians of this state. We have been both effective and lucky, so far, but how long can it last? Each year our opponents get stronger by raising more and more for their own PACs.

The suggested contribution for COMPAC is $100. We simply ask for the investment of a pittance in return for fighting tenaciously for physicians and the practice of medicine in this state. I am sure that virtually every physician reading this column has spent at least that much on a nice dinner out within the past few weeks. Can't you spare $100 to protect your patients and to protect your professional life?

Oh, sure. There are lots of reasons not to give. COMPAC gives to candidates who don't belong to your party. COMPAC gives to legislators who don't side with medicine on each and every vote. COMPAC gives to candidates in both parties. COMPAC doesn't give to enough of the candidates in the (fill in the blank) area. COMPAC didn't give enough money to candidate XYZ in the last election. One of latest reasons for not giving is, "I don't need COMPAC or the CSMS because I am joining a group and it will take care of me."

I could go on with this litany of reasons that make us miss the forest for the trees. COMPAC is designed with one purpose in mind and that is to pursue a single issue agenda, namely the advancement of physicians and their patients. Pursuing this agenda requires us follow a bipartisan strategy and donate to candidates with whom we agree on nothing else but our own single issue agenda. As I said, it even requires us to donate to candidates who have not been terribly helpful in the past. No legislator agrees with us on everything. Not even our spouses do that. We would like to give more to our favorites but this requires a greater level of participation by physicians in COMPAC. There is no group in this state with the potential clout of all 7,000 physician members of the CSMS joining COMPAC.

So now, if you have not contributed to COMPAC, what is your excuse? This is not a rhetorical question. Write to me in care of the CSMS and tell me why you have not joined. Better yet, send $100 (written on a personal checking account) to COMPAC and join your fellow physicians who have invested in the futures of themselves and their patients. How can you not? What is your excuse?

Craig W. Czarsty, M.D.
President
COMPACT
160 St. Ronan Street
New Haven, CT 06511

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

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A Sustainable Medicine

ROBERT U. MASSEY, M.D.

> The great secret, known to internists and learned early in marriage by internists' wives, but still hidden from the general public, is that most things get better by themselves. Most things, in fact, are better by morning.
>
> —Lewis Thomas.[1]

WHEN Lewis Thomas wrote this in the early 1970s we were spending 80 billion dollars annually on health care in the United States, about 8% of the GNP. Now it is more than 12 times that amount, about 15% of the GNP, and growing. Even back then he observed, "The health-care system [was] "a bewildering, essentially scatterbrained kind of business, expanding steadily without being planned or run by anybody in particular." HMOs were new, "spreading out across the country like post offices, ready to distribute in neat packages, as though from a huge, newly stocked inventory, health." He feared then, a quarter century ago, that "we will end up spending all our money on nothing but that." What he did not imagine then was that a whole crowd of robber barons would get fabulously rich in the process!

It all began slowly enough, this growth in demand for medical care. Since midcentury the ratio of physicians to population has more than doubled, in some places perhaps tripled. The rising costs of health care continue to outstrip inflation, and, although growth in these costs slowed somewhat coincidently with the rise of managed care, they have begun to go up again. Appropriations to the NIH will this year increase by three to four times the rate of inflation.

You may recall Lewis Thomas's description of the three technologies of medicine: the nontechnology, "supportive therapy," "caring for," "standing by"; then the half-way technology, expensive, time consuming, "highly sophisticated and profoundly primitive," transplantation, dialysis, coronary bypass surgery. angioplasty, chemotherapy, giving rise to "all kinds of,electric gadgetry, and whole platoons of new professional personnel"; and finally the high technology, "exemplified best by modern methods for immunization and effective antibiotic therapy." This high technology is always "relatively inexpensive, relatively simple, and relatively easy to deliver."[1]

Until recently I believed, perhaps naively, that once we had discovered the cause of a disease, we could in time devise a simple, inexpensive way to prevent it or cure it. We could repeat the marvelous feats of Edward Jenner, Albert Sabin, and Jonas Salk and wipe out, not only smallpox and polio, but everything else, including AIDS, tuberculosis, malaria, and yes, hypertension, heart disease, stroke, cancer, depression, arthritis, and drive that unholy crowd from the face of the earth, and do it all cheaply. I even said so publicly to the various cost-control outfits that were all over the place in the 1970s, and legislators who failed to comprehend why a state-supported medical school should be in the research business.

But those of us who thought that way were apparently wrong, not in the notion that, if we could save lives and stamp out disease, the whole health enterprise would dwindle, reduced to taking care of accidental, uncontrollable events. But we forgot that most new technology was, in fact, Thomas's "half-way technology," terribly expensive band-aides and bailing wire, mostly "electric gadgetry." That kind of technology increases costs, drives demand, expands the market, fascinates its users, and often diminishes civilized life. Look at Viagra!

In his most recent book, *False Hopes: Why America's Quest for Perfect Health Is a Recipe for Failure*,[2] Daniel Callahan continues his crusade for reasonable, thoughtful, tough planning decisions, and "setting limits"—this last the title of his book of a decade or so ago. He reminds us that we have put together an unsustainable medical care system, one that will finally reduce our ability to provide adequately for other social goods, such as education and universal health insurance. We have known for years that health-care costs could not continue to rise forever, that the system was running out of control, unsustainable. But the Jackson Hole group lead by Paul Ellwood, Alain Enthoven, and the insurance nabobs said no problem; managed care, "managed competition," would fix it. We felt uneasy about deliberately letting market forces into a profession that had for more than 2,000 years professed to reject them. Now discontent and unhappiness abound, our patients are angry, harassed doctors are retiring early and advising their children not to follow them into the profession, we have 41 million uninsured, many with little or no

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ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

way to pay for medical care, and costs continue to outstrip inflation. The whole "scatterbrained" enterprise is as unsustainable as ever.

Callahan, early in his book, defines what he means by "sustainable medicine."

> A sustainable medicine will have three characteristics. It will first provide the people of a society with a level of medical and public health care sufficient to give them a good chance of making it through the life cycle and of functioning at a decent level of physical and mental competence. It will, second, be a medicine that can be equitably distributed without undue strain, affordable to the society. It must, third, be a medicine that has, with public support, embraced finite and steady-state health goals and has limited aspirations for progress and technological health goals. (p 35)

A hard saying for a society fixed upon perpetual youth, perfect health, and a medical "break through" every month! Later Callahan works carefully through the requirements for reaching the goal of sustainable medicine:

> ... only (a) a population-oriented health policy, combined with (b) a strong emphasis on personal responsibility and working hard for (c) reduced dependency upon technological medicine, would be sufficient to bring about a sustainable medicine. (p 209)

The road to a sustainable medicine includes setting limits on demands for perfect health throughout an unlimited life span. Market forces driven by profit must be divorced from medicine. "[I]f the outcome of a move to the market is an unsustainable medicine, then the net result is nothing less than a communal disaster, even if many individuals and some sectors of the community are better off." (p 210)

Although Callahan has provided, in some detail, a reasonable strategic plan to avoid almost certain disaster, like the steps to avoid disaster from global warming, it will receive little support from our political masters, both in and outside the health enterprise. Self-discipline in our free-spending, indulgent Western society is mighty unpopular. Nevertheless, *False Hopes* should be read by those concerned with medicine and medical education in the years ahead; it is a scholarly trip through 19th- and 20th-century medicine's twists and turns during what the author describes as its first and second eras. We should now be laying plans for the third era. His introduction of occasional communitarian concepts is a refreshing draught after the surfeit of rights talk to which we are daily subjected from both the left and right. To move toward a sustainable health-care system will require more devotion to solidarity and equity than is common to our individualist and rights-addicted society.

If we were to accept (and one day we surely must) steady-state medicine, we would need to resolve a number of tensions between opposing polarities (p.243):

Manipulating nature *vs* Respecting nature
Pursuing health *vs* Accepting illness
Promoting public obligation *vs* Accepting personal responsibility
Seeking personal choice *vs* Tolerating imposed limits
Chasing progress *vs* Living with steady-state medicine

My concern about all this is that any notion of limiting progress, especially in biomedical technology, will awaken a lunatic fringe of Luddites who will try to restrict support for sound biomedical research on the grounds that we can't afford it, and that we know enough already. Lewis Thomas's idea of the "high technology" of medicine being both affordable and effective was right. But we are not there yet; its full bloom may be generations away. "Then what?" he asked. Callahan, and Thomas as well, I believe, would accept a life expectancy of somewhere between 75 and 82, would oppose such things as cloning and genetic engineering, especially messing around with the lethal gene, and for both the metaphor of Dr. Holmes's "The Deacon's Masterpiece, or the Wonderful 'One-Hoss Shay'" would be exactly right.

> The poor old chase in a heap or mound,
> As if it had been to the mill and ground!...
> ... it went to pieces all at once—
> All at once and nothing first—
> Just as bubbles do when they burst.

Thomas added, "This is, in high metaphor, what happens when a healthy old creature, old man or old mayfly, dies.... What a way to go!"[3]

The Germans, who have been at this business of universal health insurance since Bismarck and the 1880s, thought that by requiring everyone to purchase health insurance, and paying the premiums for those who could not afford it, and by limiting premium increases to the rate of inflation, they could control costs, create a sustainable medicine, assure general satisfaction. But all this does not stop demand, and demands, from both inside and outside the profession, put pressure on the politicians. All sorts of accommodations are made, and the cost of medical care rises again, outstripping all other social goods. And now even the Germans are looking to the market, examining, heaven help them, our managed-care fiasco.

Attitudes about life and death, health and illness, perceived individual rights, personal behavior, social responsibility—all have to change. That is a big order, especially during this time of high prosperity. To get this done, we may have to wait for the next depression.

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This Month's Reading in Review

TIMOTHY B. NORBECK

"Physicians have been unhappy with the current system for a decade. Patients have been unhappy for five or six years. Now even CEOs are unhappy because costs are rising again. If everybody's unhappy with the existing system, what better time to change it?"

Remarks of Nancy Dickey, M.D., newly installed
president of the AMA (and the first woman to
hold that position), urging managed-care reform.
New York Times (18 June 1998)

"The managed-care industry is the only industry in the country that has a congressionally mandated shield from liability."

Representative Charlie Norwood (GA),
in supporting ERISA reform.
USA Today (19 June 1998)

"There's no question that patients' rights and HMO reform will be the key political issues this election," said Democratic pollster Mark Mellman. "Some experts even predict it will dominate the next presidential election."

Christian Science Monitor (18 May 1998)

"Some 80%–90% of HMO patients are quite well, and many won't even need to see a doctor the whole year. No one else is dissatisfied with 'managed care' until they get sick. Then the problems begin for both M.D. and patient; red tape, denials, premature discharges, restrictions on second opinions from 'nonparticipating' physicians, etc. Yes, HMOs are great until you get sick."

From a physician letter to the editor,
responding to a managed-care article.
Wall Street Journal (26 May 1998)

"It was socialism, in Oscar Wilde's famous complaint, that was flawed because it would consume 'too many evenings.' In order to have adequate checks and balances, private managed care in the United States consumes too many of the doctor's evenings and entails too many promoters, marketers, attorneys, underwriters, consultants, reviewers, and shareholders—all taking too big a cut of the premium dollar up front while passing too much of the risk along to the physician. Whether socially motivated HMOs can survive with their ideals intact while competing in this environment remains to be seen."

Robert Kuttner in the *New England
Journal of Medicine* (28 May 1998)

Don't Tell Congress: Members of the European Parliament will never have to wait in line for a bathroom stall. Each has his or her own private bathroom, complete with shower. The bathrooms cost $14,790 each.

Forbes (1 June 1998)

"A pack of cigarettes costs $7.05 in Norway, a price that includes $5.23 in taxes. In Britain, a pack costs $5.27, with $4.30 coming from taxes, and a pack costs $4.75 in Denmark, where taxes amount to $4.02 per pack. A pack of cigarettes costs $1.90 on average in the U.S., where federal taxes amount to only 66 cents per pack."

Washington Post (16 May 1998)

Massachusetts Governor Paul Cellucci has ordered the appointment of a state ombudsman to advocate for patients insured by HMOs.... The ombudsman will assist the public in appealing any treatment claims denied by health plans and act as a "watchdog" for patients in the state.... Additionally, Cellucci's executive order created a "managed care advisory board at the state Department of Public Health" that will gather data and distribute an HMO consumer information guide.

Boston Herald (29 May 1998)

Eighteen New York state HMOs—including Oxford Health Plans, the Health Insurance Plan of Greater New York, and Empire Blue Cross and Blue Shield—have agreed to "comply with the Managed Care Consumer Bill of Rights," a law mandating full explanation of health plan benefits and services to customers.... The HMO's agreement was made in response to New York Attorney General Dennis Vacco's threat to file suit "unless the companies established policies to better inform consumers." A report released last month by Vacco's office found that only 18 of 31 HMOs "did provide handbooks and other contract information required by the two-year-old law."

New York Daily News (26 May 1998)

Only in America: In March, the Oregon Lottery Commission awarded a $124,000 contract to a company to advise it on how best to restore its gambling games to operating status in case of a catastrophic earthquake or asteroid collision, with a goal of having video poker back up within two hours of a disaster. Several critics suggested there might be more pressing problems after an earthquake, but the Commission pointed out that gambling generates $1 million a day for the state.

America on Line (12 June 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

It is an especially happy and welcome occasion when one of our colleagues is honored from outside the world of medicine. Morris Wessel, M.D., received special recognition last month for his life of good works in medicine, service, and scholarship. He was awarded an Honorary Degree of Doctor of Science from Connecticut College. We congratulate him and print herewith the citation accompanying that event:

CONNECTICUT COLLEGE

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MAY 23, 1998

Morris Wessel

Morris Wessel, M.D., in a lifetime of work you have exemplified the highest ideals of the medical profession and been an inspiration for generations of pediatricians.

Morris Wessel you are co-founder of the Hospice movement in the United states, and national leader in children's health issues including child poverty, the risks of lead poisoning and the importance of healthy emotional development. You earned your B.A. from Johns Hopkins University in 1939 and your M.D. from the Yale University School of Medicine in 1943. Thereafter, you began a career devoted to pediatrics, the hospice movement, and advocacy.

You have been honored by the American Academy of Pediatrics with the C. Anderson Aldrich Award in Child Development, previously awarded to Dr. Benjamin Spock. In honoring you, the Academy noted that you are "a master of the office-based observational study period" and added that your "unique quality has been to examine complex phenomena encountered in practice but not adequately covered in current textbooks or journal articles." You have also been honored with the American Academy of Pediatrics' Practitioner Research Award for being a "renaissance pediatrician and a broad-based scholar." You are staff pediatrician for the Clifford W. Beers Guidance Clinic in New Haven.

You spent your early years in New London and are the recipient of the New London Native Son Award. you are the author of *Parents Book for Raising a Healthy Child* and more than 200 other publications. You have been concerned not only with ensuring that more have a healthy beginning of life, but also a dignified end. To that end, you co-founded the nation's first hospice in Branford, Connecticut, in 1971, and you have written and spoken widely on how to help children cope with death.

Morris Wessel, pediatrician, researcher, advocate for children, Connecticut College proudly confers upon you the degree of Doctor of Science, *honoris causa.*

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Quality-of-Life and End-of-Life Decisions

Letter to the Editor: Senator Gramm et al expressed great faith in the power of the marketplace to control the cost of Medicare expenditures. The authors believed that beneficiaries should "... be given a choice among competing health-care delivery systems ... [because] ... competition in the private market for health care has helped push the growth of medical insurance costs below the growth of the Consumer Price Index."[1]

This faith in the power of the marketplace to solve the problems of our health-care system is not shared by all Americans. It is a growing consensus that the profit motive which drives the private market for health care is inhumane and has no place in medicine. As patients and voters become better informed about the forces that are dominating health care they are expressing their concerns to their legislators. This has led to increased interest among legislators to regulate managed-care organizations by guaranteeing patients choice of doctors and easier access to specialists.[2] As expected, the tightened regulations drew severe criticism from insurers because their profits may be lessened greatly. For example, in Texas recent legislation has made HMOs liable for their utilization decisions that have adverse effects on patients. Accustomed to being protected by the Employee Retirement Income Security Act (ERISA) HMOs have further reduced physicians' fees.[3] Many physicians already complain about having difficulties maintaining their office overheads, and reducing their fees further is unfair. In Minnesota, the "cradle" of managed care, experience has shown that neither managed-care organizations nor groups of private physicians have been successful in keeping health costs under control. Undue attention to controlling cost rather than changing patterns of health-care delivery has been blamed.[4]

Perhaps, as Daniel Callahan has pointed out, what is really needed to control health-care costs are cultural changes in the way we perceive the "life cycle"—if we are to create a health-care system that, in his words, is "sustainable."[5] Society may soon be faced with making difficult decisions, such as, should there be age cutoffs for dialysis or coronary bypass surgery or who gets admitted to the ICU? New technology, along with new procedures and medicines, becomes available every day. Often beneficial, it is just as often expensive and creates moral dilemmas, as mentioned earlier.

Maybe the next stage of our health-care debate will center on educating the public about these issues. In a sense they have been isolated from these difficult decisions because as physicians we have not been as clear about the limitations of medicine as we could have been. And as the evidence in Minnesota has shown, controlling health costs by paying attention only to the bottom line does not work. Managed care and independent medical groups have not been able to control costs for more than a few years at a time.

Educating patients about the realities of what medicine can and cannot do should be uppermost on medicine's agenda. Discussions of quality-of-life and end-of-life decisions are certainly just as important as controlling cholesterol and hypertension.

Edward J. Volpintesta, M.D.
Bethel

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In Defense of Linguistic Correctness

Letter to the Editor: In our zeal to support Dr. Massey's passionate defense of linguistic correctness, let us not neglect to malign the pusillanimity of the writers of dictionaries, who are ever willing to cave in to the vagaries of "popular usage." "To impact," a nonverb if there ever was one, is now listed as a nonstandard synonym for "to affect." "Disinterested," having strayed from its correct meaning of "impartial," now appears as a synonym for "uninterested." Where will it all end?

The timidity of Mr. Webster and his ilk, their refusal to hold the line, knows no bounds. As Queen Victoria most assuredly would *not* have said, "we are not bemused."

Victor A. Altshul, M.D.
New Haven

Shortfall of Physicians?

Letter to the Editor: In a recent issue of *The Lancet* (25 April 1998; 351:1265) it is reported that several countries face a shortfall of physicians that can only be alleviated by recruiting foreign graduates. The Canadian shortfall is about 1,000 physicians a year and the U.K. National Health Service presently has almost 1,000 vacancies for general practitioners.

Do you think there is some correlation between these figures and the micromanagement and government control of medicine in those countries?

James R. Merikangas, M.D.
Woodbridge

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Literary Gaffes

Letter to the Editor: It was good to learn that literary gaffes appear not only in the *New Haven Register*, but also in the *Hartford Courant.* I was pleased, also, to find that I'm not the only one annoyed when writers and speakers disregard rules of English that I had learned by the 7th grade. Maybe they didn't parse sentences in school. If they did, we wouldn't find statements like "... in selecting *my wife and I* for this honor." You are more patient than I am in the his/her roadblock to fluency. (Shep Nuland dealt with it in the introduction to one of his books, and it helped.)

A few that bother me: The police *convinced him to* throw down his gun and come out.

"etc." means *exetera!* Commentators on TV and radio didn't study Latin.

"Incredible" has become a buzz word. "My date the other night was incredible," one of our secretaries told another. Good? Bad? What?

"Mitigate" *vs* "militate"—the facts *mitigate against* this opinion.

The military man would never say "we can do thus and so ..." or even "We *have the ability to* do thus and so ..." when "We have the *capability* to do thus and so ..." sounds so much more authoritative.

It's bad enough to allow "impact" to displace "effect" and "result," but seeing it used as a verb reminds me of a condition I learned while studying gastroenterology.

Teenagers have developed a means of communicating with one another that is almost incomprehensible to me. I've included an example from the *Reader's Digest.*

"Does Shakespeare appeal to today's youth? Well, sort of ... O Romeo, O, Like, Wow" condensed from *Columbus Dispatch,* by the author Mike Harden, published in *Reader's Digest,* July 1995:117-9.

> "... But then Romeo sees Juliet and he goes, "Ah, dear Juliet, why art thou yet so fair?" 'cause, you know, if she was dead she ought to be green and starting to smell funny. And that totally bums him, so he takes the poison. *Duh!* Then you'll never guess this part. She wakes up and sees Romeo and goes, "O Happy dagger!" and kills herself.
>
> I mean, are these people serious, or, like, what?

John A. Kirchner, M.D.
Woodbridge

IN MEMORIAM

BONTKE, CATHERINE F., Baylor College of Medicine, 1982. Dr. Bontke was the medical director of the Rehabilitation Hospital of Connecticut. Previously, she served as director of the brain injury program at The Institute for Rehabilitation and Research in Houston. She was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Bontke died 11 June 1998 at the age of 42.

BUTTERFIELD, ROBERT K., Tufts University School of Medicine, 1950. Dr. Butterfield was a general practitioner in Manchester until 1970. In 1970, he became an emergency physician at Manchester Memorial Hospital and was appointed chairman of the emergency department in 1974, a position he held for 11 years. Dr. Butterfield served as the hospital's medical staff president from 1973 to 1974. He served as medical director for the Manchester and East Hartford Paramedic programs. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Butterfield died 22 May 1998 at the age of 79.

FLYNN, FREDERICK J., University of Virginia School of Medicine, 1943. Dr. Flynn, a pediatrician, maintained a private practice in West Hartford from 1949 to 1966. He was director of pediatrics at Hartford Hospital from 1966 to 1971 and was director of pediatrics at Newington Children's Hospital from 1963 to 1982. Dr. Flynn was an Associate Professor at the University of Connecticut School of Medicine. Former president of the Hartford Medical Society and the Connecticut State Chapter of the American Academy of Pediatrics, he was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Flynn died 24 June 1998.

HIBBS, MARGARET S., University of Tennessee College of Medicine. Following her post graduate study in rheumatology, Dr. Hibbs received a research appointment to the Veterans Administration Hospital in Memphis and joined the faculty of the University of Tennessee College of Medicine. Since 1988, she served in a research capacity at the Veterans Administration Hospital in Newington, as an adjunct faculty member at the University of Connecticut School of Medicine and had published numerous articles and research papers. She was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Hibbs died May 28, 1998 at the age of 47.

HUBER, H. CRANE, JR., Temple University School of Medicine, 1946. Dr. Huber, a surgeon, maintained a private practice in Waterbury from 1953 until his retirement in 1988. He was the school physician for Kaynor Technical School since its beginning and was also company physician for American Brass Company and Scovill Manufacturing Company. In addition to the Waterbury Medical Association, he was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Huber died 10 June 1998 at the age of 75.

KRAUT, HERBERT L., Harvard Medical School, 1953. Dr. Kraut practiced dermatology in Stamford from 1960 to 1984. He was a member of the Fairfield County Medical Association, where he served as a delegate to the Connecticut State Medical Society from 1972 to 1978, the Connecticut State Medical Society, where he served on the Cancer Coordinating Committee and the Occupational Health Committee during the 1960s and 1970s, and the American Medical Association. Dr. Kraut died March 1996 at the age of 67.

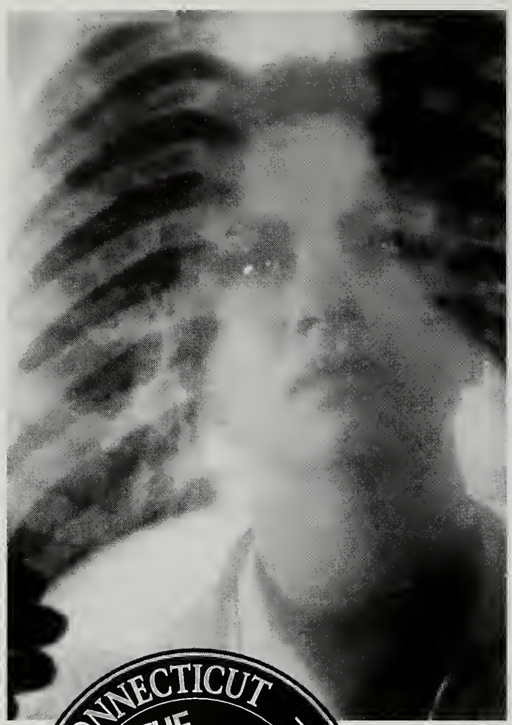
LUNDBERG, EINAR A., University of Vermont College of Medicine, 1940. Prior to his retirement, Dr. Lundberg was the medical director of American Cyanamid in Stamford for 15 years. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Lundberg died 3 June 1998 at the age of 83.

NORTON, WILLIAM S., Columbia University College of Physicians and Surgeons, 1937. Dr. Norton served as chief of staff and president of the Medical Board at St. Luke's Hospital in New York, where he was an attending physician from 1947 to 1971. He served as medical director at the Choate School from 1971 to 1976. Dr. Norton was a founding member of the Connecticut Hospice, working with hospice patients and caregivers until last year. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Norton died 21 June 1998 at the age of 87.

RICHARDS, NORMAN R., Faculté de Médecine de la Université de Lausanne, Switzerland, 1955. Dr. Richards practiced family medicine in Waterbury until his retirement in 1987. In addition to the Waterbury Medical Society, he was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Richards died 31 May 1998 at the age of 72.

STANDISH, WELLES A., Yale University School of Medicine, 1925. Following his surgical training, Dr. Standish joined the surgical staff at Hartford Hospital. He started the surgical residency program and served as director of surgery. A governor of the American College of Surgery and former president of the New England Surgical Society, Dr. Standish was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Standish died 29 May 1998 at the age of 98.

WHITE, JOHN COWLES, Harvard Medical School, 1929. Dr. White began his medical career in New Britain in 1932. He was the senior attending physician and cardiologist at New Britain General Hospital until 1941, when he became the medical director. In 1945, he and five other physicians formed Connecticut's first medical practice group, Grove Hill Clinic. From 1946 to 1964, he served as chief of medicine at New Britain General Hospital and then served as chief of staff for the next two years. Dr. White was a member of the Hartford County Medical Association, where he served as a delegate to the Connecticut State Medical Society from 1965 to 1969, the Connecticut State Medical where he served on the Committee on Hospitals from 1966 to 1971, and the American Medical Association. Dr. White died 19 May 1998 at the age of 95.



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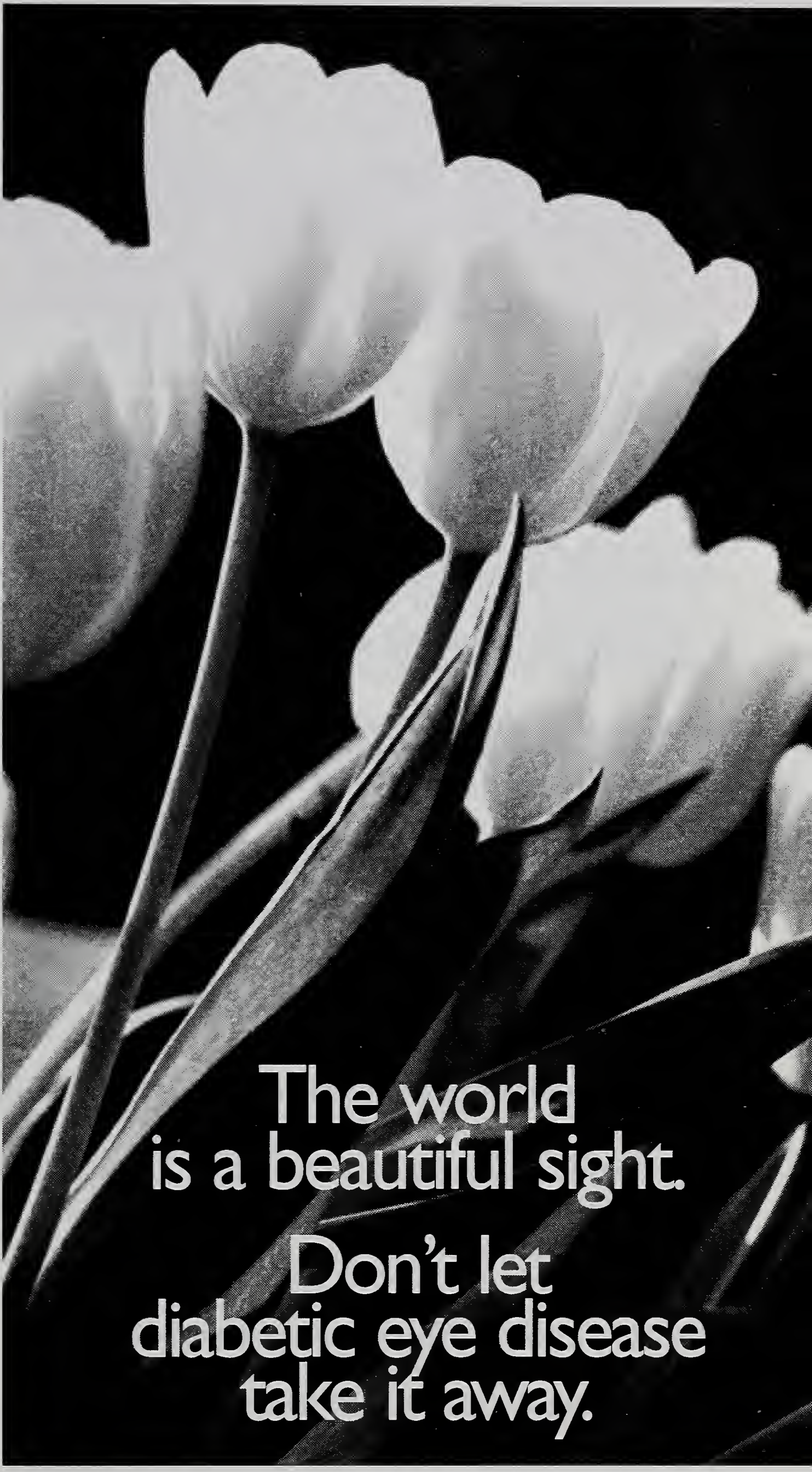

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 AUGUST 1998 NUMBER 8

scientific:

David Shames and Richard Sheinbaum 451 **Neuromuscular Oropharyngeal Dysphagia Secondary to Bone Metastases**

Thomas J. Van Hoof and W. Blake Taggart 455 **Mental Retardation and Decision Making: Balancing Autonomy and Protection**

John P. Welch, Jeffrey L. Cohen, Paul V. Vignati, Lisa W. Allen, Jeffrey S. Morrow, and Joseph J. Carter 461 **Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?**

Danbury Hospital 465 **Abstracts of Papers: Danbury Hospital, 13th Annual Joseph L. Belsky, M.D., Research Day, 13 May 1998**

Epitomes of Progress

Irwin I. Rosenfeld 475 **Important Advances in Clinical Medicine—Psychiatry**

Drug Information Update: Hartford Hospital

JoCarol McNabb, David Nicolau, Richard Quintiliani, and Charles Nightingale 483 **Trovafloxacin: Fourth Generation Fluoroquinolone**

The Medical Letter

489 **Fenofibrate for Hypertriglyceridemia**

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commentary:

Stanley M. Aronson 491 **Hold the Mayo**

Timothy B. Norbeck 492 **Why Congress Must Regulate Managed Care**

departments:

Fifty Years Ago

495 **An "Index of Curative Skill"**

The President's Page

Craig W. Czarsty 497 **Breaking Down the Walls of Cynicism?**

Reflections on Medicine

Robert U. Massey 499 **More on Sustainable Medicine**

Medical News Capsules

Timothy B. Norbeck 501 **This Month's Reading in Review**

Letters to the Editor

Elenor K. Schoen 503 **"Physician Assisted Living"**

Fowler White 503 **"Neutrinos, the Mind and the Theory of Everything"**

Stephen R. Katz 504 **Be Not Afraid!**

From the Executive Director's Office

CSMS 505 **Council Meeting**

general:

509 **Book Review**

510 **CSMS Physician Placement Service**

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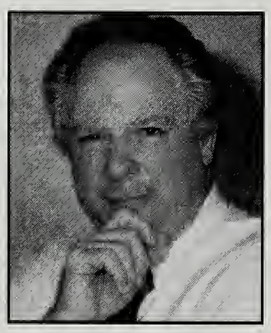

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Neuromuscular Oropharyngeal Dysphagia Secondary to Bone Metastases

DAVID SHAMES, M.D. AND RICHARD SHEINBAUM, M.D.

ABSTRACT—Oropharyngeal dysphagia in adults is secondary to either a structural lesion or neuromuscular disorder of the upper esophageal sphincter. In cricopharyngeal achalasia (incomplete relaxation of the upper esophageal sphincter), the etiology is usually either related to neck surgery or other neuromuscular disorders. We report on a rare case of neuromuscular oropharyngeal dysphagia secondary to bone metastases to the base of the skull. The patient is an 81-year-old man with prostate cancer with metastases to the sacrum. A gastroscopy was attempted to discern the etiology of his dysphagia, but the endoscope could not be advanced. A barium swallow showed cricopharyngeal achalasia, and an magnetic resonance image of the brain demonstrated bone destruction to the floor of the left posterior fossa in the region of the jugular foramen and foramen magnum. The bone destruction caused disruption of the glosso-pharyngeal and vagus nerves. Selective radiotherapy resulted in rapid improvement in his symptoms. The primary treatment of cricopharyngeal achalasia is to correct the underlying process, if possible. This case illustrates an unusual presentation of secondary cricopharyngeal achalasia caused by cranial nerve involvement secondary to bone metastases.

THE etiology of oropharyngeal dysphagia is varied, but can be divided between structural lesions and neuromuscular (motility) disorders of the upper esophageal sphincter (UES).[1] Although a careful history should lead the clinician to the correct path in most cases, further investigation is needed for the definitive diagnosis. Motility disorders include a hyper- and hypotensive UES, and abnormal UES relaxation. Abnormal relaxation of the UES includes premature closure, delayed relaxation, or incomplete relaxation (cricopharyngeal achalasia).[1] We report on a rare case of neuromuscular oropharyngeal dysphagia secondary to bone metastases to the base of the skull.

Case Report

The patient is an 81-year-old man who presented with a four-day history of dysphagia, described as immediate regurgitation of solids and liquids. Prostate cancer had been diagnosed seven years previously, and had been treated with orchiectomy, prostate radiotherapy, and flutamide. Metastases to the sacrum were noted two years ago. Physical examination revealed a thin man in no acute distress. Vital signs included a temperature of 37°C, heart rate 84 per minute, respiratory rate 16 per minute, and a blood pressure of 152/94 mmHg. His neck was supple with no nodes or masses palpable. His neurologic examination was significant for a decreased gag reflex, dysarthria, and no facial or peripheral muscular weaknesses. The remainder of the physical examination was unremarkable. Laboratory values included a white blood cell count of 3,700 per μL, with a normal differential cell count. The hematocrit was 33%, calcium 9.2 mg/dL, lactate dehydrogenase 607 IU/L, and alkaline phosphatase 445 IU/L. Roentgenograms of the chest and soft tissues of the neck were unremarkable. A gastroscopy was attempted, but the endoscope could not be advanced past the UES, and the patient was referred for a barium swallow.

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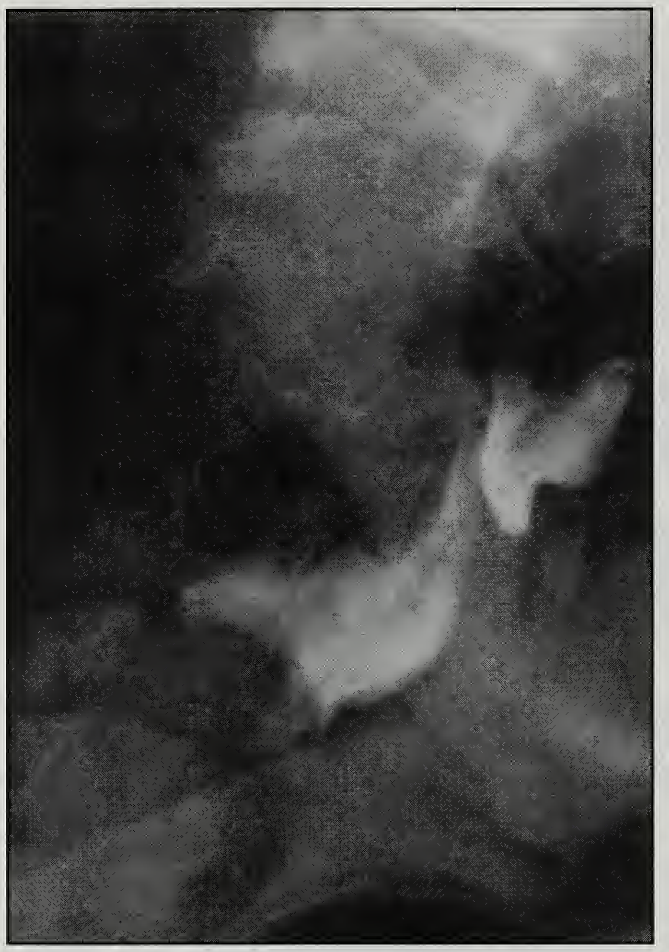

Figure 1.—Esophagogram demonstrating pooling of contrast within the hypopharynx. Note the compression effect of the contracted cricopharyngeus muscle.

The barium swallow demonstrated no obstruction, but the contrast was delayed within the hypopharynx, and cricopharyngeal achalasia was diagnosed (Fig. 1). A magnetic resonance image (MRI) of the brain and neck (Fig. 2) disclosed bone destruction of the floor of the posterior fossa on the left along the region of the jugular foramen and foramen magnum. Also noted was mild soft tissue extension inferiorly, edema in the subtemporal fossa, and alteration of the signal in the left side of the tongue consistent with paralysis of the left XIIth cranial nerve. Daily radiation treatments to the base of the skull were started, and by day five, the patient was tolerating fluids. A repeat barium swallow seven days after the onset of treatment showed a slight delay in the relaxation of the cricopharyngeus, but a clear improvement in comparison to the previous study. The patient was discharged home on day eight, able to tolerate soft foods, and with a clear improvement in his presenting symptoms of dysarthria and decreased gag reflex. On follow-up in the medical clinic four weeks after discharge, the patient reported that he was able to eat soft foods without difficulty.

Discussion

The radiographic abnormalities noted on the MRI leds to the etiology of the dysphagia. The glossopharyngeal and vagus nerves exit the skull through the jugular foramen. Bone metastases to that area of the skull caused neuromuscular dysfunction of the cricophyrangeal muscle secondary to cranial nerve disruption. The rapid improvement in symptoms following selective radiotherapy supports that conclusion.

The mechanics of swallowing include a highly coordinated action of many muscle groups and neurologic innervations. All of the pharyngeal muscles, except for the stylopharyngeus (innervated by the glossopharyngeal), are innervated by the vagus nerve. The muscles of the face (cranial nerve VII), mastication (motor root of cranial nerve V), tongue (cranial nerve XII), and the hyoid (cranial nerves V, VII, and first and second cervical) add to the complex nature of swallowing.[2] The cricopharyngeus muscle acts as a sphincter at the pharyngoesophageal junction. This sphincter protects against retrograde flow of contents in the esophagus, and is therefore normally contracted except during swallowing.[3]

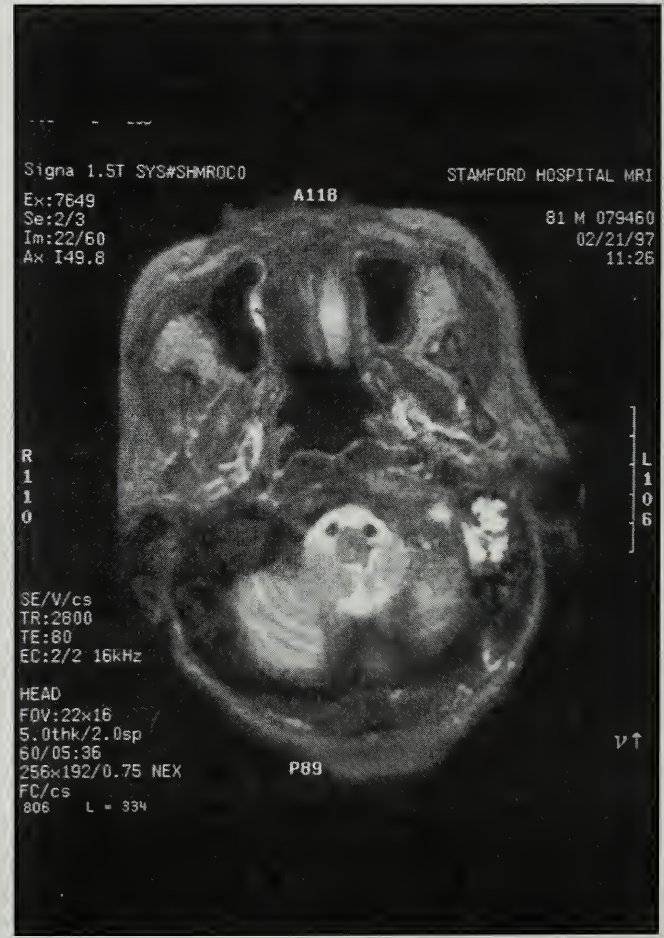

Figure 2.—MRI brain showing bone destruction of the floor of the posterior fossa on the left.

Inability of the UES to relax during swallowing and thereby not allowing food its normal passage into the esophagus, is the explanation usually given for cricopharyngeal achalasia.[4] Although the prevalence of primary cricopharyngeal achalasia is not known, it is a common finding in newborns (it usually resolves spontaneously). Most cases in adults are secondary to either neck surgery or other neuromuscular disorders.[5]

In our case the diagnosis of cricopharyngeal achalasia was originally made by radiographic examination of the UES during swallowing. It was noted that a cricopharyngeal "bar" appeared at the C6-C7 level.[6] This bar represents a transient or continuous indentation in the posterior esophagus as barium passes through.[7] The ability accurately to measure intraluminal esophageal pressures (now the gold standard for the diagnosis of UES dysfunction) has been shown not to correlate with a barium swallow.[3,8–10]

The primary treatment of cricopharyngeal achalasia is to correct the underlying process if possible. In some cases, such as dysphagia following a stroke, the swallowing problem often will improve with time. Other cases may require surgical intervention, the treatment of choice being cricopharyngeal myotomy.[8,11]

This case illustrates an unusual presentation of cricopharyngeal achalasia caused by cranial nerve involvement secondary to bone metastases. Although myotomy was not performed in this patient, the constellation of findings from the clinical history, physical examination, and radiographic information all support the above diagnosis.

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Mental Retardation and Decision Making: Balancing Autonomy and Protection

THOMAS J. VAN HOOF, M.D., M.A. AND W. BLAKE TAGGART, M.D.

ABSTRACT—Balancing autonomy with protection in caring for patients with mental retardation remains a formidable task for many clinicians. Though historical debate has resulted in an attitude supporting increased autonomy for all patients generally, and in legislation for enhanced decision making for the developmentally disabled specifically, the operationalization of such attitudes and policies lacks sufficient attention in the literature. The authors discuss three important areas of decision making as these relate to the care of patients with mental retardation: competence, respect, and multiple stakeholders; and, offer recommendations in each area to provide clinicians with some guidance in balancing the goals of autonomy and protection in clinical care when treating people with mental retardation.

Introduction

THE past three decades have seen an increased emphasis on the importance of autonomy as a bioethical principle, and a concomitant attack on the concept of paternalism in medical care.[1-3] Examples of this trend have included discussions of the struggle between beneficence and autonomy;[4] the appropriate role of paternalism in medical care;[1,4-12] and the distinction between medical and social paternalism,[6] to name but a few. The focus of attention on autonomy has heightened the awareness of clinicians and patients to this important principle, particularly for groups of patients for whom autonomy had had little meaning historically.

Parallel and complementary to the general trend supporting patient involvement in medical decisions has been a number of federal statutes, starting with the Mental Retardation Facilities and Construction Act in 1963, supporting the specific rights of people with disabilities to be involved in decisions relating to their care. The Developmentally Disabled Assistance and Bill of Rights Act of 1976 represented a strong step forward for individuals with developmental disabilities and introduced the notion that services should be commensurate with potential: "... persons with developmental disabilities, have a right to appropriate treatment, services, and habilitation ... [and that] treatment, services, and habilitation ... should be designed to maximize the developmental potential of the person."[13] Ongoing requirements have emphasized the notion of the "least restrictive setting,"[14] and have afforded individuals with developmental disabilities opportunity for input regarding placement and services.

Although most would agree and support the notion that people with developmental disabilities should be actively involved in decisions relating to their care (ie, have an appropriate degree of autonomy), the implementation of decision making rights in actual practice remains a struggle for many clinicians caring for such patients. One issue that often arises in considering the appropriate level of decision making capacity for patients with developmental disabilities is whether the individual is competent or not to make this specific decision. Another common factor relates to an over-emphasis on the decision rather than the person in situations in which the person is not competent.

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Finally, the involvement of multiple stakeholders (eg, family members, clinicians, agency workers) in such cases, with the potential for an adversarial process, remains one final issue worth discussing. This article seeks to discuss the issue of decision making as it relates to one important group of patients with developmental disabilities—those with mental retardation—and to propose some recommendations that would enhance the involvement of people with mental retardation in their own care while providing an appropriate degree of protection.

Before proceeding, two terms warrant further clarification as they are used in this paper. The authors use the term "autonomy" to mean "the capacities of persons to exercise the right ... to make their own decisions without interference from others."[15] Thus, "right" and "capacity" exist as the two key components of our adapted definition of autonomy. Assuming that all adult persons, including those with developmental disabilities, have a theoretical right to make decisions about their own bodies, this paper focuses on the latter component of autonomy—capacity. For this reason, the authors use the terms "decision making" and "autonomy" interchangeably given that decision making is really just the capacity aspect of autonomy. Meanwhile, the other important term, "respect for person," is an ethical concept that seeks to promote autonomy while simultaneously advocating for protection for those individuals who may have impairments in the area of autonomy.[16] In a sense then, respect for person incorporates both the notion of autonomy and protection under its aegis, and is a broader term than autonomy.

Mental Retardation

The diagnosis of mental retardation, applicable to 1% – 3% of the population,[17] represents a heterogeneous disorder resulting from multiple etiologies and characterized by "below-average intellectual functioning and impairment in adaptive skills that is present before the person is 18 years of age."[18] The diagnosis itself, even with a severity qualifier (eg, mild, moderate, etc.), is not necessarily predictive of a person's level of function or decision making ability. Most people with mental retardation live relatively independent lives with minimal assistance, but some need more help, ranging from case management to institutional care. Though the vast majority (~85%) of patients with mental retardation fall in the "mild" range,[17] many patients have guardians or conservators to make health- care decisions for them. The presence of a comorbid psychiatric diagnosis, the existence of medical problems, and the quality of social support can also influence the level of function and decision making ability experienced by a person with mental retardation.

Parallels with Other States and Disorders

People with mental retardation do not stand alone as a group of patients for whom the appropriate degree of patient autonomy is often in question. Other traditional groups at risk for "paternalistic" treatment include: children and adolescents; patients in acute rehabilitation; psychiatrically ill patients; and the elderly. Though not covered in this paper, one additional group at risk includes prisoners.

Because of their developmental stage and insufficiently developed sense of judgment, generally children and adolescents do not enjoy the same measure of autonomy as competent adults. In discussing informed consent, the Committee on Bioethics of the American Academy of Pediatrics appropriately argues that "decisional capacity" and "legal empowerment" are two requirements necessary for children to make medical decisions about themselves.[19] Silber, discussing the problems of anorexia nervosa and substance abuse, justifies treating adolescents "paternalistically" when an adolescent's life is at stake or when autonomy is impaired.[12] Similar to some people with mental retardation, children and adolescents may not fully appreciate life-and-death decisions, and may not be fully capable of an informed decision regarding complex matters. Unlike mental retardation however, where innate cognitive abilities remain static, the condition of being a child or adolescent is temporary; so, part of the justification for overriding autonomy now is to preserve the opportunity for mature decision making later.[1]

Caplan cogently argues for the appropriate role of paternalism in caring for patients in the acute stages of rehabilitation after suffering severe levels of impairment, and offers a variety of factors to differentiate this type of care from the typical "contractual model" of informed consent: treatment over an extended period of time; involvement of multiple treaters and caretakers; diversity of settings; and insufficient time to adjust, to name but a few.[1] Though like mental retardation in respect to the first three factors listed above, patients in acute rehabilation differ from those with mental retardation in that the goal exists to move them to a point where they are able to make decisions for themselves (ie, paternalism is temporary); whereas, time needed to adjust remains much more relevant to acute rehabilation than mental retardation.

Acutely psychiatrically ill patients represent a third potential group of patients for whom protection is often necessary at the expense of autonomy.[20] The appropriate use of involuntary commitment statutes and physician emergency certificates are two prime examples of paternalism in action. Again, as in caring for children and patients in acute rehabilation, the ultimate goal is to achieve stability, and, in so doing, support autonomy. Thus, temporizing measures explain most breaches of autonomy in acute psychiatric care.

The final group of patients vulnerable to paternalism may best approximate patients with mental retardation. Older individuals, particularly those suffering from progressive dementia, may have their autonomy overridden in order to promote beneficence.[10,21] Though dementing processes may result in waxing and waning cognitive abilities (and, in turn, perhaps waxing and waning autonomy), the goal of paternalism is not to promote autonomy but rather to provide protection. However, elderly patients with diminished capacity may differ from patients with mental retardation in that they may have left advance directives that continue to speak for them; whereas, patients with mental retardation of sufficient severity to impair autonomy generally do not have a premorbid baseline of higher functioning.

Competence

Though one should carefully consider the issue of "competence" when working with a patient with mental retardation, the mere presence of the condition does not necessarily confer any predictive value.[17] According to Grant and Steele, in Massachusetts the court defines "competency" as "... the ability to relate one's own values to the proposed treatments and to possible outcomes in a rational manner rather than any ability to make 'objectively good' decisions." Competency assessments should focus on specific issues, and always begin with the question "competent to do what?" People with mental retardation, as well as all patients, may be competent in some decision areas, but incompetent in others. Massachusetts appears progressive in fashioning guardianships to apply only to areas of demonstrated need rather than global judgments of competence or incompetence.[22] Thus, just as being mentally retarded does not necessarily preclude autonomy in decision making; being incompetent in one area of decisions does not always predict incompetence in other areas.

Another important consideration in assessing competency in people with mental retardation is distinguishing factors that are static from thoses that are not. Psychosocial functioning and decision making capacity may vary over time in individuals with mental retardation. Given the considerable prevalence of comorbid psychiatric conditions affecting 40% to 70% of all people with mental retardation,[17] one must be careful not to make long-term determinations of competence during the acute phase of a psychiatric illness. Also, acute stress may influence competence in individuals with developmental disabilities. Reassessment of competence is appropriate if more factors than mental retardation coincide with the evaluation; otherwise, one may disrupt the delicate balance between autonomy and protection, and introduce too much paternalism into the treatment relationship.

Autonomy *vs* Respect for Person

The notion of "respect for persons" may be a more appropriate and relevant ethical principle than "autonomy" to have in mind when working with incompetent patients with mental retardation (and perhaps even with some competent patients with mental retardation). Respect for persons, as an ethical concept, incorporates not only the notion of an individual being "capable of deliberation about personal goals and of acting under the direction of such deliberation" (which is autonomy), but also that "persons with diminished autonomy are entitled to protection."[16] A fine line often exists between respect and protection, and for many decisions—particularly those not strictly medical—a large gray area may exist. Complex decisions around real-life situations may not be easily answered by a competency assessment (unless the patient is consistently and globally incompetent). Keeping in mind respect for the person may be more helpful than considering who has the right to make any particular decision, and may minimize the power struggle in a group deciding for an incompetent person.

Connecticut's statute on sterilization provides an excellent example of respect for persons in action.[23] For individuals unable to give adequate informed consent for a sterilization procedure, the process has in place multiple safeguards (eg, application, review, hearing, etc.) to protect patients from a sterilization procedure not in their best interest. On the other hand, patients with limited capacity for informed consent require little justification for refusing this procedure. Thus, it is easy to say "no" but difficult to say "yes." Put another way, a patient unable to consent to the procedure may, in the same instance, be able to refuse it. Such a statute provides protection yet still respects the individual's decision making ability however limited.

Multiple Stakeholders

Often, the care and daily living of people with mental retardation involves many individuals, including family members, agency workers, case workers, and clinicians. All involved have a vested interest in the patient, and may develop strong feelings about their roles in decisions relating to care. At times, conflicts may develop over decisions made, particularly if the decision by one group or individual has ramifications for the duties or expectations of other parties. A subtle struggle for power may develop that would be detrimental to the patient's care. Unintentionally, often the focus of discussion becomes *who has the right to make a particular decision* rather than *what is in the patient's best interest.* These situations can arise regardless of competence or guardianship, but often occur with patients who are deemed to be incompetent in one or more areas. The skill of a psychiatrist or mental health professional in bringing a group of stakeholders to a consensus about what is best for the patient may be extremely important in striking a balance between autonomy and protection. The following case exemplifies the breakdown of cooperation between a group of stakeholders that resulted in a bad outcome for one patient with mental retardation.

DL is a middle-aged, single male with a history of mild-moderate mental retardation who lives in one northeastern state. He receives services from his state's mental retardation agency, which provides him with treatment and supervised housing (the patient lives in his own apartment with minimal supervision), and a family member exists as his legal guardian since the courts have found him incompetent to manage his own affairs. Controversy has arisen because the state agency has sought to place DL in a more structured, protected environment because of consistent behavioral problems including: showing young children condoms; threatening to throw matches near people pumping gas at a local gas station; allowing prostitutes to live with him in his apartment with a question of unprotected sex; being victimized by theft; and presenting to the hospital emergency room on several occasions after inserting sharp objects into his urethra. DL also inappropriately utilizes crisis services in the evenings. These problems have been consistent and not amenable to a host of interventions, and have prompted the state agency to advocate for a more structured living arrangement. DL and his guardian have resisted such suggestions on the grounds of personal liberty (ie, want least restrictive setting), and have convinced the probate court not to override their decision on such matters. Shortly after the court decided not to overturn the guardian's decision, DL caused a fire in his apartment that damaged the entire housing unit and threatened the lives of the other inhabitants.

Though the case raises some relevant questions about whether the guardian is acting in DL's best interest, and about the potential conflict between justice and beneficence, the authors describe the case to focus attention on the underlying power struggle that led to the unfavorable outcome. The fact that the decision found its way into the court probably reflects the inability of a consensus to have been reached by those involved in DL's care, and certainly suggests some conflict existed between the guardian and the state agency. A more favorable outcome for DL would likely have been some compromise between the different advocates concerned. Unfortunately, DL remains in the middle of this debate, and still needs the services and support of the different parties. The conflict will likely interfere with future deliberations about what is in DL's best interest, and is not consistent with the mentality of respect for person necessary for optimal care.

A physician, most often a psychiatrist, may have a unique opportunity to manage group dynamics and help the "interdisciplinary team" redirect the focus from power to patient. Though recognizing the need for a legal guardian or conservator ultimately to be responsible for decisions, often a group caring for a patient with mental retardation could devise a plan of care superior to one developed by any one member of the group. Also, a number of individuals representing different vantage points coming to a decision is more likely to ensure a balance between autonomy and protection. Guardians are often relieved to share the burden of decision making with professionals; however, the key exists in establishing rapport. Physicians too may be reluctant to share in medical decisions for which they are liable; however, acting in a cooperative team environment may lead to more informed decisions and actually decreased liability risk. This "interdisciplinary team" approach, advocated by Hauser, requires that psychiatrists be willing to share decisions heretofore the purview of the doctor-patient relationship: "The psychiatrist spends time not only with the client but also with the agency staff, advocates, and family members. The psychiatrist relies on, benefits from, supports, and educates these other team members."[14] This approach also demands that professionals travel in order to meet in a group. Meeting face-to-face for a discussion, rather than relaying information between sources, may decrease misunderstandings due to miscommunications and misinterpretations. Other mental health professionals involved in the case and with training in group dynamics may also be comfortable serving as team leaders advocating for the patient through an effective group process.

Recommendations

The authors offer the following recommendations for further consideration regarding the balance of autonomy and protection when caring for patients with mental retardation. The three recommendation areas include competence, respect for persons, and the interdisciplinary team.

Clinicians working with patients with mental retardation should have a low threshold for considering the issue of competence. Despite advocating for a low threshold, clinicians should not assume that patients with mental retardation are not competent merely by way of the condition itself, nor make predictions about competence on the basis of IQ or level of function at any one point in time. Requests for competency assessment should be as specific as possible, and states should try to fashion conservatorships and guardianships around the needs of each individual. Finding a quick yet accurate tool for all clinicians to assess competence exists as an important need. Given the evolving nature of comorbid psychiatric states and psychosocial circumstances with mental retardation, one should consider periodic review of competence to ensure adequate protection yet preserve appropriate decision making power. Being incompetent does not detract from the value of involving the patient in group discussions about care. A patient may be impressed with the numbers of people who care for her and the careful process of making decisions, and these factors may enhance compliance. Many care decisions involve preferences that even incompetent patients can express. Finally, having the patient present for the discussion will help the group focus on the patient rather than the politics.

Keeping in mind the concept of respect for persons rather than autonomy may also foster better care for patients with mental retardation. The balance between decision making and protection is always delicate, and respect for person, though a broader construct than autonomy, may minimize group struggles by concentrating on the person rather than the decision. Starting each group discussion with a concession about the gray areas inherent to the process may remind members of a group that recommendations are seldom right or wrong but somewhere in between. Respect for persons would appeal to family members, guardians, advocates, and clinicians alike in that it appeals to notions of autonomy and protection at the heart of genuine concern.

The interdisciplinary team approach remains the most challenging component of the process of ensuring a balance in decisions for incompetent patients with mental retardation. The leader of the group needs to be an individual who is respected for his or her expertise regarding care, one who is involved in the specific case in question, and one who holds some power regarding decisions. All three factors make it difficult for this same person to advocate for a group approach to care. Often, psychiatrists may be in the best position for this role; however, other individuals may be well suited as well. The leader should show humility and embrace the team approach. The team should focus on a review of all relevant information pertinent to a decision before discussing options and taking positions. As the group discusses views and quite possibly differing opinions, a focus on the underlying themes of compassion and respect may help overcome interpersonal dispute. Devising plans that incorporate some part of each person's suggestions will also facilitate consensus. Contingency plans often achieve this goal. Finally, having meetings at different sites can be instructive to decision makers, and may optimize feelings of collegiality.

Conclusion

Caring for patients with mental retardation can be a clinically rewarding though ethically challenging endeavor for health professionals. The need to strike a balance between autonomy and protection for such patients requires a careful consideration of data and insights from multiple sources. The process of making complex decisions with multiple stakeholders is fraught with potential conflict; however, multiple stakeholders may provide the necessary checks and balances essential to adequate protection for those with limited or absent autonomy. The key to success in making the best decision with a patient lies in assessing his or her level of decision making capacity, keeping the idea of respect and protection in mind for those not competent, and balancing the views of multiple stakeholders when making group decisions. We hope that continued discussion and research in this important area of applied clinical ethics will result in a model that better promotes the involvement of people with mental retardation in their care.

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Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?

JOHN P. WELCH, M.D., JEFFREY L. COHEN, M.D., PAUL V. VIGNATI, M.D., LISA W. ALLEN, PH.D., JEFFREY S. MORROW, M.D., AND JOSEPH J. CARTER, M.D.

ABSTRACT—Fifty-nine patients undergoing elective major lower gastrointestinal surgery were entered into a prospective, randomized trial between January 1993 and July 1994 comparing the effectiveness, side effects, and hospital costs of postoperative epidural anesthesia (Group 1, n=29) and intramuscular narcotic injections (Group 2, n=30). Epidural catheters were inserted by a team that supervised catheter care and infusion rates in the postoperative period. The nonepidural group received intramuscular injections on a regular basis. Patients filled out visual analog scales to measure levels of pain (1=minimal, 10=maximal) every eight hours. Patient activity, bowel, and urinary function were recorded by the nursing staff. Control of pain (as measured by the daily average visual analog score) was more effective in Group 1 ($P<.001$) on postoperative days 1-3 (1.3 *vs* 3.6 on day 1, 0.7 *vs* 2.6 on day 2, 0.9 *vs* 3 on day 3). There was no significant difference in mean values between groups 1 and 2 with respect to first ambulation on the hospital ward, onset of liquid diet, intake of solid food, first spontaneous voiding, first bowel movement, length of hospitalization, or charge of hospitalization ($13,439 +/- 7,452 *vs* $11,821 +/- 6,630). We conclude that epidural anesthesia significantly lessens incisional pain following major elective lower gastrointestinal surgery when compared to analgesic injections alone. However, while not statistically significant, the overall charge was increased by 14% in the epidural group. This finding should be examined in light of the relatively low pain level in patients receiving narcotic injections alone.

Introduction

CURRENT management of postoperative pain involves a variety of medications and delivery routes. The traditional method of intramuscular injections of narcotics has the disadvantage of varying levels of analgesia, leading to decreased activity, prolonged ileus, and possible respiratory complications.[1-3] Continuous epidural infusion of medications by an indwelling epidural catheter has been an accepted method of postoperative analgesia. Epidural catheters have been proven effective in noncolonic surgery, providing superior patient comfort.[4-7] Less pain may lead to earlier ambulation, better incentive for spirometer use, and decreased pulmonary and thrombotic complications. Hypothetical advantages, including decreased ileus and leakage rates, were hoped to lead to decreased hospital stay.[8-13] The potential drawbacks of epidural analgesia include urinary retention, epidural bleeding or hematoma, catheter failure, and increased cost. Several studies have proven epidural catheters to provide a safe and effective means for pain control.[14-18]

However, the literature is inconclusive. The studies that have evaluated epidural analgesia have been mainly retrospective and have failed to account for elective as opposed

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The work for this article was performed at Hartford Hospital in Hartford. It was supported by the Institutional Review Committee at Hartford Hospital. The paper was presented as a poster in the meeting of the American Society of Colon and Rectal Surgeons in Seattle, June 1996.

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to emergency operations.[4-6,17,19] The theoretical advantages of epidural analgesia have not been proven in clinical practice. In addition, these studies did not account for cost, and evidence of the cost/benefit of each modality is lacking.[20] To determine if epidural medications provided superior analgesia in our institution, we conducted a prospective study involving patients undergoing elective abdominal surgery. We hoped to evaluate the level of patient comfort, speed of recovery, frequency of complications, and overall cost with either continuous epidural or intramuscular injections of narcotics. Our goal was to define a superior technique for pain control after elective colonic surgery.

Methods

With approval of the institutional review committee, a prospective study was initiated in January 1993. All patients were ASA class I or II, and underwent elective major colorectal surgery under general anesthesia. Ninety percent of the operations in the two groups were elective colectomies. There were isolated instances of abdominoperineal resection, coloanal anastomosis, and ileoanal pouch procedures. Patients having emergency operations were excluded. All patents undergoing these operations under the directions of three surgeons (JC, PV, JW) were asked to participate in the trial on a voluntary basis. Written and oral informed consent was obtained preoperatively in the office setting. The procedure, discomfort, and reasonable foreseeable risks, and benefits were described in full in a written document.

A thorough history (including respiratory or cardiac disease and use of immunosuppressive or anticoagulant medications) was obtained from all patients.

Patients were randomized, ie, assigned by chance prior to surgery using a table of random numbers, to receive either an epidural catheter (EC group, n=30) or intramuscular injections with narcotics (IM group, n=29). All epidural catheters were inserted by a specialized pain team, which confirmed placement and supervised epidural care and function. No patient from the EC group received any epidural medications during the operation. Both groups received analgesics starting in the recovery room. The EC group received a continuous infusion of 0.1 mg/mL of morphine and 0.1% bupivacaine. No patients in this group required intramuscular or oral supplements because of insufficient pain relief. Doses were adjusted by the pain team. The IM group received intramuscular morphine or meperidine hydrochloride, which was delivered every three to four hours on a p.r.n. basis. All patients received postoperative care on a standard surgical ward and were assessed at regular intervals by the nursing staff.

Pain intensity was determined by the patients using a digital analog scale (0=no pain, 10=maximal pain) every eight hours. Additional parameters included: 1) level of activity, measured by the first ambulation in the room and down the hall; 2) bowel function, measured by the frequency of emesis, the time of first flatus, first stool, and first liquid and solid food intake; 3) first postoperative voiding; 4) respiratory status, determined by nursing assessment, and the need for pulmonary toilet, bronchodilators, or reintubation; 5) complications, including myocardial infarction, arrhythmia, heart failure, pneumonia, deep vein thrombosis, or pulmonary embolism; and 6) length and cost of hospitalization, excluding surgical fees.

Data were recorded on standardized forms and entered into a database for tabulation. Statistical analysis of the categorical data was by the χ^2 test without correction for continuity. All other variables, including time for recovery and cost, were analyzed by the independent samples t-test. Statistical significance was determined with a two-tailed critical value of $P<.05$.

Results

Between January 1993 and July 1994, 59 patients (22 women, 32 men) underwent elective gastrointestinal surgery. The procedures included colon resection, low anterior and abdominoperineal resection, coloanal and ileoanal anastomosis, and Hartmann closure. The average age was 58 years. Postoperative pain control was delivered with either an epidural catheter (EC group, n=30) or intramuscular injections with narcotics (IM group, n=29). Patients in the EC group had more effective pain control (as measured by the visual analog scale) on postoperative days 1-3 (day 1: 1.3 *vs* 3.6; day 2: 0.7 *vs* 2.6; day 3: 0.9 *vs* 3.0, $P<.001$). There was no significant difference between the groups in first ambulation, onset of liquid or solid diet, first spontaneous voiding or bowel movement, or length of hospitalization (Table 1). No episodes of respiratory compromise or other complications occurred in either group.

Discussion

Pain control with either intramuscular injections or epidural infusion appears to provide adequate patient comfort. However, the EC group reported better pain control during the first three postoperative days. We could not prove a difference in recovery or complication rate in either group. The theoretical advantage of decreased postoperative ileus with an epidural catheter was suggested (EC group 2.8 days, IM group 3.5 days), but could not be proven statistically significant ($P=0.10$). Earlier intake by the EC group did not correlate with earlier bowel function or decreased length of stay. There were no catheter-related complications or episodes of respiratory depression. We believe surveillance by a skilled pain team will decrease morbidity associated with indwelling epidural catheters.

The perception of less pain, however, may lead to more spontaneous activity. Less pain was believed to lead to

Table 1.— Recovery and Cost Analysis, Measured in Postoperative Days

	Epidural	IM Narcotics	
Ambulation	1.56	1.58	P=0.94
Diet	2.8	3.5	P=0.097
Bowel function	3.4	3.39	P=0.97
Spontaneous void	3.2	2.6	P=0.15
Complications	No statistical difference		
Length of stay	7.65	7.56	Not studied
Hospital cost	$13,439	$11,821	P=0.38

earlier ambulation and better incentive spirometer use, decreasing pulmonary and thrombotic complications.[1-3,12] However, we did not find a statistical difference between the two groups. All our patients received routine postoperative nursing care with emphasis on ambulation. The success of the IM group suggests that attentive nursing care will motivate patients to undergo activity even with mild pain.

Epidural catheters were associated with an increase in the overall hospital charges (EC group $13,439, IM group $11,821). Hospital charges were obtained from the billing office following discharge. Charges were compiled from factors such as nursing care, administered medications, and operating room expenses. Professional fees of anesthesiologists and surgeons were not included. As hospital costs fluctuate in the era of managed care, this difference may need to be assessed in light of the adequate pain control provided by either method.

This study was not blinded to the patients or the recorders, which leaves it subject to observation bias. Since the information was recorded by someone not directly involved with interpreting the data, we do not think observer bias affected out results. We did not include intravenous patient-controlled analgesia systems, so we cannot directly compare continuous intravenous *vs* epidural infusions. Since we exclusively used morphine and bupivacaine, we cannot exclude other epidural medications that might provide superior analgesia or postoperative recovery. We also cannot comment whether epidural infusions started before or during an operation will alter postoperative recovery, but that finding has been suggested in the literature.[21]

In summary, epidural catheters can be used safely to provide postoperative analgesia following major gastrointestinal surgery. The benefit of improved patient comfort did not lead to significantly earlier recovery, but may lead to increased cost. We cannot advocate the exclusive use of epidural analgesia for elective colonic surgery, although further studies are warranted.

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Abstract of Papers: Danbury Hospital 13th Annual Joseph L. Belsky, M.D., Research Day 13 May 1998

The following 13 abstracts were selected from 38 submitted abstracts.

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^{14}C Urea Breath Test: Test of Choice for Noninvasive Screening for *Helicobacter pylori* and Verifying Eradication After Antibacterial Therapy

SADAR ZAMAN, M.D., SHIV GUPTA, M.D., WILLIAM JOHNS, M.D.,
AND JOSEPH FIORITO, M.D.
Departments of Pathology and Laboratory Medicine (Nuclear Medicine)
and Medicine (Gastroenterology)

The association of *H. pylori* with peptic ulcer disease (PUD) has revolutionized the way we view and treat PUD. In the United States, the prevalence of infection ranges from less than 10% in Caucasians under age 30 to over 50% in those over age 60. The presence of *H. pylori* infection is strongly associated with peptic ulcers and antral gastritis. Eradication of this infection may effectively eliminate ulcer recurrences. Chronic infection is associated with a four- to six-fold increased risk of gastric adenocarcinoma as well as an increased risk of gastric malt lymphomas.

H. pylori may be detected by a variety of tests including endoscopy with gastric biopsy and histologic demonstration of the organism. A blood test for IgG antibodies to *H. pylori* is also available. The results may remain positive for more than 12 months after infection has resolved, and thus (in up to 60%) does not necessarily reflect active infection.

^{14}C urea breath testing is a new test available at Danbury Hospital which allows detection of active *H. pylori* infection. A retrospective study involving 50 patients who had undergone testing in 1997 was performed. The population included 23 (46%) males and 27 (54%) females ranging in age from 25-82 years. All of the patients presented with dyspepsia symptoms. Twelve patients (24%) had positive ^{14}C urea breath tests for *H. pylori* infection, while 38 (76%) had negative tests. Twenty patients (40%) had a history of positive *H. pylori* biopsies, 30 patients (60%) had positive serology. Twenty (40%) had previous treatment for *H. pylori* and had either persistent or recurrent symptoms. Of these 20 patients, nine (45%) had positive ^{14}C urea breath tests and 11 (55%) had negative tests. Patients with positive breath tests were therefore treated with different protocols resulting in improvement in symptoms, whereas in patients with negative tests, other etiologies were considered as cause of dyspepsia.

The ^{14}C urea breath test is a safe, rapid, noninvasive method of determining active *H. pylori* infection. It may be used in the initial investigation of patients with dyspepsia, as well as follow-up of patients who have persistent or recurrent symptoms after initial treatment to evaluate effectiveness of eradication of *H. pylori* infection.

Clinical professor (Dr. Gupta), assistant clinical professor (Dr. Johns), University of Connecticut School of Medicine.

Induction of Labor with Oral Misoprostol in Intrauterine Fetal Demise

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Intrauterine fetal demise is a complication of pregnancy that presents multiple problems to both the physician and the patient, particularly the issue of deciding the best way to deliver such patients.

Prostaglandin (PG) E2, vaginal or intracervical preparation, has been used with some success; however, it has a high rate of side effects (nausea, vomiting, fever, diarrhea). These side effects make the patient, already emotionally drained from the event, even more uncomfortable.

Oral misoprostol, a synthetic analog of PG E1, produces the same result (medical evacuation of uterine contents) as PG E2 preparations, without the associated side effects of the latter. This, together with its route of administration, makes oral misoprostol an attractive approach for this pregnancy complication.

We present four cases of intrauterine fetal demise in which oral misoprostol, 200 μg, was used with good results. The interval between the first dose of oral misoprostol and delivery ranged from 129 minutes to 635 minutes (average 304 minutes), no side effects were noted, and two out of the four patients required only one dose of oral misoprostol.

We suggest the use of oral misoprostol, 200 μg every four hours until delivery in cases of intrauterine fetal demise, or even in mid-trimester termination of pregnancy for severe congenital anomalies. In cases of nulliparous patients, the use of cervical laminaria may make the interval to delivery shorter.

Associate clinical professor of obstetrics and gynecology (Dr. Silberman), Yale University School of Medicine

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Atypical Glandular Cells of Undetermined Significance in Papanicolaou Smears at Danbury Hospital

LEONEL EDWARDS, M.D., CARLOTA GAY RABINSTEIN, M.D.,
LOIS GRIGG, AND HANI EL-FANEK, M.D.
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Data to define the clinical importance of atypical glandular cells of undetermined significance (AGUS) on cervicovaginal smear, until recently, have been scarce, thus preventing a good definition of the importance of such a finding. Recent studies have indicated that a diagnosis of AGUS represents a significant risk for major uterine pathology, and authors have recommended colposcopically directed biopsies, endocervical curettage, and, in older women, endometrial biopsies. In order to determine the risk that a diagnosis of AGUS carries at our institution, we have undertaken the present review.

Methods: A computer search was initiated of diagnoses of AGUS at Danbury Hospital's Department of Pathology and Laboratory Medicine from June 1996 through June 1997.

Results: The number of cases reviewed in the section of cytology between 1993–97 totaled 24,600. Four hundred twenty-six (1.9 %) patients with approximately 1,368 smears were identified. Ages ranged from 18 to 80 years. Two hundred twenty-four (49.1%) patients were followed with repeat smears only. One hundred thirty-two (29%) were followed with both repeat Papanicolaou smears and biopsy, and 14 (3%) were followed only with biopsies. Eighty-four (18.4%) had no record of follow-up at our institution. Sixteen (3.5%) patients followed with smears persisted with an AGUS diagnosis. Of the patients followed with a biopsy, 43 (9.4% of the total) patients had significant uterine pathology as shown by biopsy. The diagnoses included human papilloma virus/cervical interepithelial neoplasia, *in situ* adenocarcinoma of the cervix, and disordered proliferative endometrium.

Conclusion: AGUS is an infrequent diagnosis in the literature (<1%), and at our institution (1.9%). Although the recommended follow-up method is a repeat smear (78% of the cases), when biopsied, a cytologic diagnosis of AGUS results in significant uterine pathology in 29.5% (43 out of 146) of the cases. Due to the association of the diagnosis of AGUS with significant uterine pathology, follow-up biopsies are recommended, especially in those cases with persistent abnormality.

Early Identification with Early Intervention Is an Effective Means of Improving Nutritional Status of Hospitalized Patients

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Malnutrition in the hospitalized patient has been linked with increased morbidity, mortality, and increased costs. The literature has indicated that elderly patients and patients with chronic diseases are often undernourished at the time of admission. This study proposed to assess patients admitted to the medical service at the time of admission for risk of malnutrition, and promote prompt intervention when necessary.

Charts of 65 patients discharged in January and February 1997 were reviewed. Selection was limited to all patients 65 years of age and older with lengths of stay (LOS) ≥ 4 days. The survey revealed that 27/65 (41%) of the patients had documented nutritional deficiencies during their hospital stay. Fifteen had low albumin levels (range 1.7-3.4 mg/dL). Sixteen (25%) were identified on admission as having poor or fair nutrition, yet nutrition services were consulted for only six (9%) of the patients within 24 hours of admission. Further, seven patients with LOS of five to six days were not seen by nutrition services at all, even though some had documented nutritional needs. Five (7.7%) of the patients had pressure ulcers.

A nutrition assessment tool developed by an interdisciplinary team was utilized to identify patients at high risk for nutritional deficiencies at the time of admission. This tool, completed at the time of admission, assessed six items such as recent unintentional weight loss of >10 pounds, less than 50% of usual oral intake for > 3 days, persistent vomiting, or admitted lactating or pregnant for a condition unrelated to pregnancy. If any factor was identified, the questionnaire was immediately faxed to the dietary department. Additionally an easy process to refer at-risk patients to nutrition services was implemented. A chart review of discharges in January and February 1998 (n=157) was conducted. Using the new screen, 30% (47/157) of patients met the high-risk definition. Most frequent interventions were the addition of oral supplements, calorie counts, and attention to food preferences.

Albumin levels were drawn on 25 of the identified high-risk patients (mean 2.55 g/dL, range 1.8–3.7 g/dL). Of interest, 11 albumin levels were drawn on patients not identified at risk (mean 3.3 g/dL). This difference demonstrates the accuracy of the screening tool (P=.001).

Using a simple screening device can identify patients at risk for malnutrition and therefore utilize dietary services more appropriately. Early identification leads to nutritional support in a timely manner. Mean time of evaluation by a dietitian decreased from 4.5 days to 3.1 days. Too many uncontrolled factors in this study prohibited linking the improved nutrition with decreasing length of stay. Also, effectiveness of the nutrition support could not be quantified—only six patients had prealbumin levels drawn after refeeding.

3D Conformal Radiation Therapy Treatment for Prostate Cancer: An Analysis of Acute Toxicity

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AND KATIE DORSEY-KENDRICK
Radiology Department (Radiation Therapy) and Department of Medicine (Oncology)

The curative treatment of prostate cancer with radiation has recently undergone a major change with the introduction of 3D conformal therapy treatment planning. This change has allowed higher doses of radiation to be delivered to the prostate, and as a result an increased cure rate is expected. This report analyzes the acute toxicity of that treatment and compares it to standard radiation therapy which as been the main treatment modality for more than 30 years.

Using 3D conformal therapy, the radiation dose was increased by nearly 15%. With that increase in dose, one would normally expect an increase in the complication rate, but this has not occurred. An analysis of 24 patients treated at Danbury Hospital for prostate cancer was performed. Twelve patients were treated with 3D conformal therapy. The incidence of genitourinary side effects during the course of radiation decreased from 50%, using standard radiation treatment, to 8% with 3D conformal therapy. This decrease was both in the number of patients with side effects as well as in their severity. The genitourinary complication rate was unchanged but its degree of severity was decreased, with 33% of patients treated with standard radiation therapy having a grade III toxicity as compared to 8% with 3D conformal treatment.

3D conformal therapy, when used for treating prostate cancer, has less acute toxicity than standard radiation therapy treatment.

Stereotactic Core Biopsy for the Diagnosis of Mammographically Detected Breast Lesions: A Two-year Experience at Danbury Hospital

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Departments of Pathology and Laboratory Medicine, and Radiology

Breast cancer is the most common major malignancy in American females and is the second (after lung cancer) most common cause of cancer death. Mammography is the best modality for the early detection of breast cancer, and has been shown to reduce mortality from this disease by 30% to 40% in women older than age 50. Most of these lesions are benign, though some have radiologic features that mimic malignant lesions. For a definitive diagnosis to be made in such cases, biopsy is necessary. Stereotactic core biopsy (SCB) is a minimally invasive, cost-effective, alternative technique to open biopsy that does not compromise diagnostic reliability. Recent studies have shown a national annual cost saving of approximately $200 million with SCB over open surgical biopsy.

If the SCB diagnosis is benign and in keeping with the mammographic findings, the patient is spared an open surgical biopsy. It is in this group of patients that SCB is most useful. The procedure also provides a definitive diagnosis of highly suspicious lesions so that clinicians may begin discussion of treatment alternatives with patients, and perhaps avoid one unnecessary surgical procedure.

One hundred thirty-eight SCBs were performed on 111 patients from November 1994 to December 1996. Patients ranged in age from 26 to 84 (mean 52) years. Seven patients (6.3%) had a previous history of breast carcinoma (three ipsilateral). An average of six cores were submitted for histologic examination. Histopathologic findings were as shown in the table below:

Radiological Findings		Histopathologic Findings			
		Normal	**Benign diseases**	**Carcinoma**	**Other**
Noncalcified masses	91 (66%)	17 (19%)	50 (55%)	18 (20%)	6 (6%)
Masses and calcifications	3 (2%)	—	2 (67%)	1 (33%)	—
Calcifications	44 (32%)	12 (27%)	16 (37%)	15 (34%)	1 (2%)
TOTAL	138 (100%)	29 (21%)	68 (49%)	34 (25%)	7 (5%)

Twenty-five patients (22.5%) underwent subsequent surgery (excisional biopsy and/or mastectomy). In the 21 patients (84%) with a diagnosis of carcinoma on SCB, subsequent surgical excision confirmed the diagnosis of malignancy **(no false positive diagnoses).** In two cases (8%), excisional biopsy/mastectomy confirmed the diagnosis of benign proliferative breast disease. In the remaining two cases (8%), SCB was nondiagnostic, and subsequent surgical excision revealed radiation changes in one case, and a calcified fibroadenoma in the other. There were **no false negative** SCB with respect to malignancy. In the surgically excised carcinomas, tumor size ranged from 0.5 up to 7.0 (mean 1.5) cm.

In conclusion, SCB is a useful addition to mammographic screening in diagnosing breast carcinoma at an early stage. In addition, by accurately and confidently diagnosing benign breast lesions, unnecessary surgery is avoided, reducing the cost and patient morbidity.

Instructor in pathology (Dr. Sieber), University of Connecticut School of Medicine.

School-based Health Centers (SBHC) as a Health-care Delivery System: Preliminary Observations

MELANIE BONJOUR, M.S., JOHN H. GUNDY, M.D., AND JANICE HARRISON, M.S.N., A.P.R.N.
City of Danbury School-based Health Center

Opening its doors in 1994, the School-based Health Center at Danbury High School was established to address the increasing medical and psychosocial health-care needs of the adolescent population.

Since receiving an out-patient clinic license, the center staff have worked arduously to position the clinic as a recognized program of excellence dedicated to improving the physical and mental health condition of the community's adolescent population. Through aggressive outreach, networking, and public relation strategies designed to reach students, their parents, school staff, the broad medical community, and social services providers, the SBHC staff have gained the recognition and confidence of its target population as evidenced by daily utilization rates.

Presently, 1,205 Danbury High School students, representing roughly half of the entire student population, have the required permission from their parent or guardian to use the confidential services provided by a multidisciplinary team including a nurse practitioner, therapist, and medical assistant. Clinic services complement existing community services such as physicians, mental health providers, child protection and juvenile justice agencies, reproductive health programs, sexually-transmitted disease clinics, and pregnancy prevention programs. Students lacking a primary-care physician are referred to an appropriate provider.

Between 1 September 1997 and 17 December 1997, the clinic recorded 541 visits. Of these visits 160 were for acute medical illness, 100 for emotional issues, 109 for gynecologic problems, pregnancy, or sexually transmitted diseases, 100 visits were for health education, and 72 for miscellaneous signs and symptoms. Although this list shares some similarities with a visit to a primary-care office, important disparities include the provision of health education in the areas of nutrition, violence prevention, and reproductive health, mental health counseling and referral as needed in a nonthreatening "medical" environment, treatment of infections including those that are sexually transmitted; and emphasizing the critical importance of prevention.

Wellness on Wheels (WOW™) Van
A Paradigm to Improve Health-care Access in Danbury

JACK S.C. FONG, M.D., PATRICIA REAPE, B.S.N., YIRA P. SANCHEZ, M.A.,
IRENE LITWAK, B.A., AND KATHRYN KINASEWITZ, B.A.
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City of Danbury Welfare and Social Services Department

Barriers to health-care access are extremely costly to the community in human terms when patients are suffering with potentially avoidable illnesses, and in economic terms when more resources are necessary to treat illnesses at a more advanced state. With rare exceptions, house calls are no longer made by physicians. Accordingly, the first and most important barrier to health-care access is the need for patients to commute to health-care service facilities. A mobile outreach medical service was implemented in Danbury in the last days of July 1997 with the goal of eliminating a transportation barrier to health-care access.

We reviewed the clinical services provided by the WOW van in a seven-month period from August 1997 to February 1998. During this period, clinical services were provided during 546 patient visits. The ethnic make-up of these patients was 33% White, 49% Hispanic, 13% Black, and 5% others. Most of the patients (59% of 546) were in the pediatric age group. For these 324 pediatric patients, 48% were for school physicals, 13% for immunization, 12% for illnesses, and 12% for sports physicals. For the 222 adult patients, 35% requested influenza vaccine, 32% were for illnesses, 24% for blood pressure checks, and 5% for physicals. Eighty doses (91% of adult vaccinations) of influenza-vaccine were given to adults, whereas pediatric immunizations included 28% for polio, 26% for mumps, measles, and rubella, 21% for diphtheria and tetanus, and 10% for diphtheria, tetanus, and acellular pertussis (DTaP). Of the 51 Mantoux purified protein derivative (PPD) skin tests, six (12%) were noted to be positive. Social service counseling was provided on-site to 246 (45% of visits) patients with most being eligible for assistance. Most of the patient visits, 386 (71% of 546), had either no medical insurance or established primary-care providers. Information was obtained from each patient on the reason for choosing the mobile medical service.

The WOW van has been able to provide clinical services to patients by reducing the barriers of transportation need and no medical insurance. Other barriers which were overcome and which motivated patients to seek service at the mobile van included the inability to have a timely appointment with the established primary-care provider, no established primary-care provider, noncoverage by the medical insurance, institutional policies (procedure policies), and new arrivals. In doing so, the medical services provided by the WOW van achieve the goal of improving clinical service access and of early intervention.

Associate clinical professor of pediatrics, Yale University School of Medicine and clinical assistant professor, Allegheny University of Health Sciences (Dr. Fong), Nurse Coordinator of the WOW™ Van (Mrs. Reape), immunization outreach workers (Mrs. Sanchez and Mrs. Litwak), and medical case worker (Mrs. Kinasewitz).

The Relationship Between Provider Type and Immunization Rate in Preschool-age Children

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Immunizations against infectious diseases are an efficient and cost-effective component of primary, preventive health care for children. The Comprehensive Childhood Immunization Act of 1993, part of President Clinton's Childhood Immunization Initiative, was designed to eliminate financial barriers to immunizations (*MMWR* 1994; 43:57–60). The type of health-care provider has been one factor found to influence completion rates of primary series immunization in preschool-age children.

This study examined immunization rates of preschool-age children in western Connecticut. Retrospective data from four public (n=289) and six private (n=533) provider sites were obtained. Immunization status for the vaccine combinations of four diphtheria, tetanus, and pertusis, three polio, one measels, mumps, and rubella (4:3:1) and four diphtheria, tetanus, and pertusis, three polio, one measels, mumps, and rubella, and three *H. influenzae* type b (4:3:1:3) at 19, 24, and 35 months were calculated.

Comparing the public clinics to the private practices, the immunization completion rates for 4:3:1 were: 77% *vs* 76.5% at 19 months, 87.9% *vs* 87.6% at 24 months, and 93.1% *vs* 91.8% at 35 months. There were no statistically significant differences. Similar results were found for the 4:3:1:3 series. A similar study in 1995 yielded comparable results (Burke and Fong, Childhood Immunization Programs; Proceedings of the Tenth Annual Joseph L. Belsky, M.D., Research Day, May 1995). Both studies suggest that immunization rate is not related to provider type in this community.

Recommendations for future research would be to examine immunization rates in relation to other risk factors such as ethnicity, type of health-care insurance, socioeconomic level, maternal age, birth order, number of children in the family, and parent's knowledge base.

Bone Resorption Rates in Children Correlated with Dietary Calcium Intake and Consumption of Soft Drinks with Phosphoric Acid

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The primary objective of the study was to measure bone turnover as reflected by the urinary excretion of a specific and sensitive marker, pyrilinks-D, in young children, and to correlate it with their nutritional status, serum calcium levels, and dietary calcium intake. The overall goal was to assure that the calcium metabolism of children was within normal limits.

Eighteen children between two and 12 years old participated in the study. Parents were asked to complete detailed diaries of all oral intakes for their children over a 48-hour period. At the end of that period, a urine sample was obtained for the analysis of pyrilinks-D, which measures the excretion deoxypyridinoline crosslinks, indicators of bone resorption. Pyrilinks-D is a crosslink of type 1 collagen which is released during bone resorption, excreted unmetabolized in urine and is unaffected by diet. Measurement of pyrilinks-D in urine offers a specific and sensitive assessment of bone resorption. A blood sample was obtained for the measurement of ionized calcium.

In six children, the pyrilinks-D values were abnormally high. All six children had low dietary calcium intake. In three children, the diet included soft drinks with phosphoric acid, excessive intake which is considered a risk factor for the development of hypocalcemia.

In 12 children, the pyrilinks-D values were within normal limits. However, the dietary calcium intake in eight children was also low. All 18 children studied had normal levels of serum ionized calcium and urinary excretion of calcium.

In summary, 14 out of 18 children in this study had low dietary calcium intake and six children with low calcium intake had increased rate of bone resorption.

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The Morphologic Spectrum of Ultrastructural Ciliary Changes in Patients Undergoing Nasal Brush Biopsy: A Retrospective Clinicopathologic Review

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Cilia at the epithelial surface of conducting airways protect the lungs through their pivotal role in the clearance of mucus and potentially injurious inhaled particles. Clearance requires coordinated ciliary movement, a function that depends in turn on specialized microstructures, including microtubules and dynein arms that are assembled into the axoneme, a functional unit subserving motion. Several studies have demonstrated that congenital ultrastructural abnormalities of cilia result in impaired ciliary motility, a clinical syndrome referred to as primary ciliary dyskinesia. These patients typically present with recurrent sinus and pulmonary infections. The classical defect described in sinus and primary ciliary dyskinesia is complete or partial absence of inner and/or outer dynein arms. Other abnormalities include defective radial spokes and microtubular transposition defects. A more recently described morphologic finding is random axis orientation of cilia. In the latter disorder, structurally normal cilia exhibit random orientation with respect to each other, leading to asynchronous ciliary beating.

We retrospectively reviewed the clinical and pathologic findings of 31 consecutive nasal brush biopsies performed on 29 patients with chronic cough and/or history of recurrent respiratory tract infection between January 1996 and December 1997. Criteria for biopsy included chronic cough (greater than 14 days) with no response to anti-inflammatory medications and bronchodilators. Two patients had a repeat biopsy, one because the initial biopsy was inadequate and one as follow-up for absence of cilia due to metaplasia of the respiratory epithelium. Eighteen patients were males. Patients ranged in age from three months to 40 years (mean six years). Age at onset of symptoms ranged from birth to 13 years. All patients received a course of empiric antibiotic treatment prior to the procedure and were clinically free of infection at the time of biopsy. None of the patients had *situs inversus* and all 11 patients evaluated for cystic fibrosis had normal sweat chloride results. There was a family history of chronic upper respiratory tract infection, asthma, and/or allergy in 14 patients (48%). Two older symptomatic siblings of a patient with abnormal cilia were biopsied.

Eighteen biopsies (58%) revealed normal morphology, five (16%) demonstrated abnormal microtubular configuration consistent with chronic infection, five (16%) exhibited loss of axis orientation, and a single case (3%) showed absent dynein arms. One biopsy lacked cilia due to metaplasia and one biopsy was inadequate for evaluation. In comparison with the literature, we observed a higher incidence of random axis orientation and a similar low incidence of absence of dynein arms. Overall, more than one-third of the biopsies in our series showed some morphologic abnormality. Although it is currently debated whether some of these abnormalities (eg, random axis orientation) may be acquired rather than primary, we suggest that their mere presence is sufficient to produce impaired ciliary clearance, at least temporarily. We conclude that nasal brush biopsy is a valuable tool in the evaluation of patients with chronic cough or recurrent respiratory tract infection and may influence short-term management of these patients.

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Four-year Experience at Danbury Hospital with Fine Needle Aspiration Cytology of the Salivary Glands: A Cytohistologic Correlation

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Fine needle aspiration (FNA) has become a reliable diagnostic tool for evaluating salivary gland masses. With this technique it is possible to determine whether such masses are neoplastic or nonneoplastic, benign, or malignant. Accurate FNA diagnoses can obviate the need for costly surgery and its potential morbidity.

We retrospectively reviewed salivary gland FNA specimens received at Danbury Hospital during a recent four-year period (1994–97), for which there were subsequent surgical excisions for cytohistologic correlation. During this period, there were 27 patients who underwent 29 salivary gland FNAs (23 parotid FNAs, six submandibular gland FNAs). Two specimens (6.9%) were unsatisfactory for interpretation due to lack of cells or drying artifact. Five of the FNA specimens (17.2%) were satisfactory but limited by either suboptimal preservation or scanty cellularity.

Of the 19 (65.5%) FNAs diagnosed as benign, 17 surgical specimens (89.5%) confirmed a benign lesion, and two specimens (10.5%) showed a malignancy (one acinic cell carcinoma, one malignant lymphoma = false negative cytology readings). In four patients (13.8%) with a suspicious or positive FNA for malignancy, all four surgical excisions confirmed a malignancy (three primary carcinomas, one metastatic carcinoma); ie, there were no false positive FNAs. In five FNAs (17.2%), the cytologic diagnosis was indeterminate (cannot exclude malignancy); three of these surgically excised masses were benign lesions, and two were malignant (lymphomas).

The specific lesions most accurately diagnosed by FNA were benign mixed tumors (6/6 cases or 100%); Warthin's tumor (4/7 cases or 57.1%); and acinic cell carcinoma (2/3 cases or 66.7%). The most problematic lesions to diagnose by FNA were malignant lymphomas (two unsatisfactory FNAs, one benign FNA, one indeterminate FNA).

Excluding indeterminate and unsatisfactory FNAs, the sensitivity of the procedure for malignancy was 57.1%, and the specificity was 100%.

Conclusion: Fine needle aspiration biopsy of salivary gland is a valuable diagnostic tool and has impact on treatment of these lesions. This test was 100% accurate for the diagnosis of benign mixed tumor and had 100% specificity for malignancy. However, sensitivity of diagnosing malignant lesions was low (57.1%) in part due to difficulty in detecting low-grade malignancies.

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Androgen and Epithelial Growth Factor Expression in Prostate Cancer: A Search for a Predictor of Hormonal Therapy Outcome

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Department of Pathology and Laboratory Medicine

Patients with prostate cancer may present with advanced clinical disease amenable only to hormonal therapy. Androgen receptors (AR) play a pivotal role in supporting a hormonal sensitive phenotype in prostate cancer cells. Researchers have observed that in time the hormonal sensitive phenotype is lost in prostatic tumor cells and in consequence they become resistant to hormonal therapy. This is thought to be mediated by the destruction of hormonal responsive cells and subsequent replacement with hormonal resistant cells that have acquired an advantageous new mechanism for maintaining their growth. In studies performed on hormonal resistant prostate carcinoma it has been found that expression of epidermal growth factor receptor (EGFR) by the malignant cells is associated with a phenotype resistant to hormonal therapy.

Success in trials using estrogen and progesterone receptor imnmunostaining for predicting response to hormonal therapy in breast cancer has prompted similar studies in prostate carcinoma. Regretfully the role of AR immunostaining as an outcome predictor in the use of hormonal therapy has been controversial at best. Some studies deem the trials of no value, while more recent ones have demonstrated a predictive value. The new studies have associated a negative prognosis for patients with tumor cells lacking AR immunostaining in relation to AR positive tumors. In order to characterize further the relationship of AR and EGFR in prostatic carcinoma, 50 cases of patients with known prostatic carcinoma where selected from Danbury Hospital's prostatic tumor registry. Twenty-five had documented recurrence while the other 25 had no documented recurrence. The archival tissue sections included lymph node sections, core biopsies, and prostatectomy specimens.

Results: Fifteen cases were discarded due to loss of tissue sections during processing, which left 35 cases that were successfully stained with both AR and EGFR. Twenty cases (57.1%) had documented recurrence with a mean AR score of 200. Eleven (55%) of these cases were positive for EGFR. Fifteen cases (42.9%) had no documented recurrence with a mean AR score of 253 and seven (47%) were positive for EGFR. When the staining patterns were compared with the Gleason scores the following results were seen: 24 cases were categorized as moderately differentiated (Gleason scores 5–7), of these 10 (41.7%) had documented recurrence. The mean AR score was 190 and 12 (50%) were positive for EGFR. Five cases were categorized as poorly differentiated (Gleason score 8–10), of these four (80%) had documented recurrence. The mean AR score was 170 and four (80%) were positive for EGFR. Four cases were lymph node specimens only where the Gleason score was unavailable and two were unconfirmed, well-differentiated cases.

These results are encouraging since there appears to be a correlation with frequency of EGFR positivity, lower AR scores, and higher-grade tumors. There also appears to be lower AR scores and higher percentage of EGFR positivity when we compare cases with documented recurrence *vs* cases with no documented recurrence. Further studies are needed to characterize completely the relationship. Image analysis and immunostaining for mutated AR and EGFR will be useful in the process of achieving this goal.

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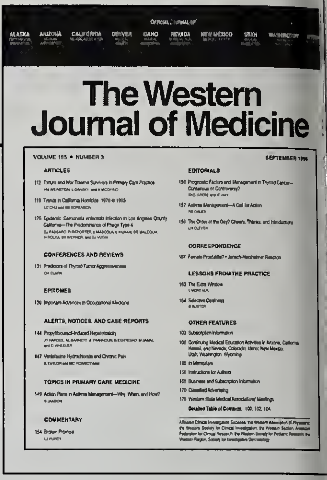

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Important Advances in Clinical Medicine

Psychiatry

IRWIN I. ROSENFELD, M.D., Section Editor

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in psychiatry. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in psychiatry that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Psychiatry of the California Medical Association, and the summaries were prepared under the direction of Dr. Rosenfeld and the Panel.

Advances in Mood Stabilizing Medications

IN the past decade, lithium's limitations as an acute and prophylactic treatment for patients with manic-depressive illness have been recognized. In addition, studies have revealed that about 50% of patients may show only a partial therapeutic response and inadequate prophylactic effect. Certain diagnostic subtypes (dysphoric mania, rapid cycling) have notably poor response rates to lithium therapy, and a substantial number of patients cannot tolerate its side effects or are unable to achieve blood levels that are necessary for complete suppression of symptomatology. This experience has necessitated the study of adjunctive and alternative treatment options to lithium.

Several anticonvulsants have emerged as major mood stabilizing alternatives to lithium therapy for bipolar illness. Data on carbamazepine and valproate indicate that while they appear to prevent manic and depressive episodes in patients inadequately responsive to lithium carbonate, they may not be sufficient for monotherapy. Two newer anticonvulsant agents, gabapentin and lamotrigine, have shown promise in the treatment of patients with bipolar disorders. Both gabapentin and lamotrigine differ from other mood regulators in two major ways: (1) their reported frequent effectiveness for treating resistant patients, and (2) their relatively benign side-effect profiles that make discontinuation due to side effects rare.

Gabapentin increases gamma aminobutyric acid (GABA) turnover and whole blood serotonin, increases breakdown of glutamic acid, and modulates norepinephrine and dopamine *in vivo*. Case reports have described its potential psychiatric indications in bipolar disorder, panic disorder, generalized anxiety disorder, and behavioral dyscontrol. The postabsorption half-life is five to seven hours with rapid crossing of the blood brain barrier. The usual starting dose of gabapentin is 300 mg once a day; the dose is increased and rapidly titrated every three to five days to the mood stabilizing dose, which is most often between 900–2,700 (up to 4,800 reported) mg per day typically taken in divided doses. Therapeutic effect is noticed from within a week up to a month. Gabapentin is generally well tolerated. The most common side effects are sedation, dizziness, unsteadiness, nystagmus, ataxia, fatigue, tremor, and diplopia, which stop when the drug is stopped.

Lamotrigine acts upon the voltage-dependent sodium channels, resulting in inhibited release of the excitatory neurotransmitters glutamate and aspartate, and stabilization of the neuronal membranes. Early reports suggest that

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lamotrigine may be beneficial in patients with treatment-resistant bipolar disorders, including mixed and rapid cycling illness. Its use in treating unipolar depression and anxiety disorders has not been extensively studied. The inhibition of glutamate may suggest a role for lamotrigine in mania following ischemic stroke. Usual initiating dose of lamotrigine is 25 mg once or twice a day, and this is increased by 25–50 mg every one to two weeks, to reach the usual effective dose range of 100-200 mg per day. Therapeutic effect is generally noticed within a month of starting treatment. The most commonly reported adverse effects of lamotrigine are dizziness, diplopia, ataxia, blurred vision, nausea, and vomiting. A severe morbilliform or maculopapular rash, developing within the first six weeks which is related to starting dose and escalation of titration, can be a special clinical hazard (rate in adults one in every thousand patients with higher incidence below age sixteen). These effects subside when medication is discontinued, but can be problematic to treat.

The principal advantage of gabapentin and lamotrigine over lithium is that routine serum monitoring of drug levels is not essential during therapy. However, as with all bipolar patients, one should be aware of a possible paradoxical switch to mania or provocation of rapid cycling. Also, while gabapentin may be safely used in combination with depakote and carbamazepine, their doses need adjustment when lamotrigine is initiated. Valproic acid should be reduced in dosage before starting lamotrigine to decrease inhibition of metabolism and reduce the risk of rash. Due to enzyme induction, the dose of carbamzepine may need to be reduced when lamotrigine treatment is initiated. The relatively recent use of gabapentin and lamotrigine for mood disorders limits the information regarding their long-term therapeutic efficacy, and potential emergent side effects.

Other modalities being studied as mood stabilizers include calcium channel blockers, and thyrotropin releasing hormone (TRH) plus other endogenous neuropeptides. Calcium channel blockers like verapamil and nimodipine are showing special promise for rapid and ultra rapid cycling. Preliminary findings have suggested that the dihydropyridine class of L-type calcium channel blockers, which includes nimodipine, isradipine etc., compared to the phenylalkalamine verapamil may have greater mood stabilizing effects, and potential as an alternative or adjunct to lithium. Preliminary data on TRH indicate possible acute antidepressant, antianxiety, and antisuicide effects.

Although the search for safer alternatives to lithium therapy in affective disorders is increasingly promising, further research of the newer mood stabilizing medications is warranted in order to establish their safety and efficacy.

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Traumatic Disorders—Contemporary Directions

EMOTIONAL reactions to trauma have been recorded since ancient times. In this century, the study of World War I veterans ("shell shock"), World War II consequences ("traumatic neurosis"), and later DSM-I (Gross Stress Reaction), DSM-II ("Transient Situational Disturbance"), Holocaust Survivors ("Survivors' Syndrome"), and DSM-III (PTSD) all constituted additions to a crystallized modern understanding of trauma reactions.

Since 1980, when Post Traumatic Stress Disorder (PTSD) became part of the official psychiatric nomenclature (DSM-III), a concerted effort has been made by specialists in psychiatric trauma to legitimize PTSD as a complex psychiatric disorder. Trauma can result in a range of disorders. The most commonly associated conditions with trauma are: PTSD, Acute Stress Disorder, other Anxiety Disorders, Mood Disorders, Somatization Disorders, Dissociative Disorders, Substance Abuse, and Adjustment Disorders. On the other hand, early childhood exposure to severe trauma more often results in affective psychopathology with little resemblance to PTSD. The type of traumatic psychopathology may be determined by the interaction of factors: type of trauma, age of impact, preexisting biological vulnerability, and possibly the complexity of affected brain mechanisms.

Diagnosis of Post Traumatic Stress Disorder represents the prototype of traumatic disorders. The symptomatology includes a classical triad of symptoms: a) the re-experiencing of the traumatic event, b) both persistent avoidance of stimuli associated with the trauma and numbing of general responsiveness, c) symptoms of hyperarousal (difficulty falling asleep, insomnia, irritability, angry outbursts, etc.). These symptoms occur after the exposure via experiencing, witnessing, or confronting an event that is perceived as threatening and is accompanied by intense fear, horror, and helplessness. Prevalence of PTSD is 7.2% in the generation population. Between 50% and 90% of patients with PTSD have comorbid disorders such as anxiety, depression, and alcohol abuse.

Other traumatic disorders include acute stress disorder, a condition that resembles PTSD but is characterized by a one-month duration (following the trauma) and includes significant dissociative symptoms. Anxiety disorders (more often panic disorders and generalized anxiety) are often the main psychiatric manifestation after traumatic stress. Most anxiety disorders occur more often in combination with other diagnoses rather than "pure culture" clinical forms. While, for example, major depression may not exhibit a different picture after a known traumatic stress, a history of traumatic stress may add additional biological abnormalities and may thus influence significantly the outcome of treatment.

After major traumatic events such as a catastrophe affecting an entire community, PTSD is relatively rare. Emotional manifestations of some kind are common, however. The majority of traumatized individuals will present a transient benign reaction characterized by terror, a sense of unreality, some depersonalization, some re-experiencing, transient anxiety, a sense of loss, and some preoccupation with images of the trauma that subsides within about three to four months. Risk factors for patients to PTSD after a community trauma include past psychiatric history, family psychiatric history, genetics, personality style such as neuroticism, introversion, personality disorder, history of trauma, low socioeconomic status, low intelligence, and even a family history of trauma.

PTSD, the prototype of traumatic disorders, is accompanied by biological markers such as an increase in blood pressure, pulse, glucocorticoid receptors, T3, and analgesia and reflect a marked sympathetic automatic overdrive, and a decrease in cortisol, alpha 2 adrenergic receptor activity, and stage three and four of sleep. In addition, acute stress is characterized by significant elevation of cortisol. Individuals suffering from chronic PSTD, on the other hand, have blunted plasma cortisol.

Recent and preliminary studies show that PTSD patients in veterans' hospitals have an average of 15 severe traumatic events in their lifetimes. Thus, in comparison to controls, individuals who develop PTSD are more likely to have had previous trauma. Finally, variants of PTSD occur. "Compassion fatigue," a form of traumatic disorder, may develop in health and mental health professionals who care for patients with PTSD; "Disorder of extreme stress, not otherwise specified" (DESNOS or "Complex PTSD"), a condition that includes symptoms of PTSD associated with severe psychiatric complications, ie, bipolar symptoms, psychosis, hallucinations, etc. also occurs. Secondary traumatization is another variant and refers to the occurrence of traumatic symptoms, more often PTSD, in individuals exposed to or who live with victims of traumatic stress.

In PTSD the process of memory consolidation may lead to continuous retraumatization, rendering PTSD a self-maintained condition similar to an autoimmune disorder. Early administration of beta blocking agents (limiting the adrenergic overdrive which is implicated in traumatic memory consolidation) and SSRIs (fluoxetine, sertraline, paroxetine, fluvoxamine), which work both on re-experiencing and avoidant symptoms, are now standard medical intervention. Long-term use of minor tranquilizers is not indicated. Comorbid disorders have to be addressed at the same time (eg, substance abuse). Most often clinicians are using a combination of dynamic and behavioral psychotherapy. Recalling the traumatic events in therapy or exposure to "reminders" has to be done carefully and gradually; therapists usually learn the amount of discomfort that such patients can tolerate. Other treatment modalities, eg, EMDR (Eye Movement Desensitization Reprocessing) seem to have numerous enthusiasts but still remain to many authors controversial.

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When Chest Pain, Shortness of Breath, and Palpitations Are Not Due to Cardiopulmonary Pathology

IT is not uncommon for the primary- care physician, cardiologist, or emergency physician to see patients presenting with acute onset of chest pain, shortness of breath, palpitations, choking sensation, diaphoresis, trembling, paresthesias, lightheadedness, abdominal distress, and fear of dying, only to find, after extensive and expensive workup, that there is no cardiopulmonary pathology present. Such patients often receive the diagnosis, "rule-out myocardial infarction," or "chest pain of unknown etiology." Panic disorder is characterized by recurrent and unexpected panic attacks (composed of at least four of 13 symptoms, 10 of which are listed above, and also include chills.

Panic disorder is defined by recurrent and unexpected panic attacks (composed of at least four of 13 symptoms, including chills or hot flashes, fear of losing control or going crazy, and derealization or depersonalization) with at least one month of excessive concern about having another panic attack, or behavioral changes resulting from the attacks that are not substance-induced (eg, precipitated by stimulants) and are not due to medical conditions (such as cardiac or vestibular disorders, hyperthyroidism, hyperparathyroidism, pheochromocytoma, or seizures.) Limited symptom attacks have fewer than four symptoms and are usually shorter and less severe. Panic attacks usually happen quickly (escalate in less than one minute and peak in less than 10 minutes) and typically last for 30 to 60 minutes, although some last for several hours. Nearly half of patients with panic disorder also have agoraphobia (fear of being in public places).

Panic disorder is common, with one-year prevalence at 1.5% of the population and lifetime prevalence at 2.5%. Women account for more than two-thirds of patients. Peak onset is from the late teens to mid-30s, although it may come on at any age. There is a four to seven times greater incidence in first degree relatives.

The course of panic disorder is usually chronic, with waxing and waning, although one-third of patients go into complete remission. Comorbid depression is common; two-thirds of panic disorder patients have concurrent major depressive disorder at some point in their illness, and one-third at any point in time. Depressed patients with panic disorder have a much higher suicide rate than those without panic disorder. Alcohol abuse occurs in one-third of panic disorder patients.

Various studies have pointed to α_2-adrenergic receptor dysfunction, postsynaptic serotonin receptor supersensitivity, blunted growth hormone response to Clonidine, and asymmetric blood flow and metabolism in the hippocampus (left lower than right) noted on PET scan. One study showed an elevation of neuropeptide Y in panic patients: neuropeptide Y is closely associated with noradrenergic activity in the central and peripheral nervous systems.

Hypochondriasis is common in panic patients. An average patient with panic disorder has 27 different unexplained symptoms. In various studies, 15% of patients in a vestibular disorder clinic and 20% of patients with dizziness had panic disorder, and panic patients were found to have a high incidence of gastrointestinal disturbance. Among patients referred for pulmonary function testing to a major medical center, 41% were found to have panic attacks, 11% were diagnosed with panic disorder, and 67% of patients with chronic obstructive pulmonary disease were found to have concurrent panic disorder. Of those patients seeing cardiologists for chest pain, 30% to 60% with negative workups have panic disorder; of those seeing gastroenterologists for irritable bowel syndrome 33% to 45% have panic disorder. While only 0.2% of those undergoing workup of pheochromocytoma actually have this condition, 67% have panic disorder.

Treatment of panic disorder has focused on antidepressants, benzodiazepines, and psychotherapy. Imipramine was found in several studies to have an excellent track record in the treatment of panic disorder with significant effects at moderate (1.5 mg/kg/day) to high (3 mg/kg/day) doses, with dropout rates due to side effects 15% and 35% for moderate and high doses, respectively. Clomipramine at similar doses has also been shown to be very effective; other tricyclics and trazodone appear to be less effective. Monoamine oxidase inhibitors (MAOI), especially phenelzine, have shown similar efficacy. Due to the high side effect profile of tricyclics and MAOIs, and their high rate of fatality when taken in overdose, studies in the past few years have examined newer antidepressants. Of the selective serotonin re-uptake inhibitors (SSRI) greater success has been noted with fluvoxamine and paroxetine than with sertraline, and least with fluoxetine, which was nevertheless better than placebo. Nefazodone has also been shown to be effective for panic disorder, especially at standard (460 mg/day) *vs* low (243 mg/day) doses, and better than imipramine (202 mg/day). Bupropion has been shown to be ineffective. Studies on venlafaxine and mirtazapine are underway.

All benzodiazepines have shown efficacy in the treatment of panic disorder, but many patients will show significant side effects with doses needed to control the disorder. Benzodiazepines are not recommended at the onset of an attack, since the action of the medication, which averages 30 to 60 minutes, is similar to that of the duration of the panic attack itself. However, in the few panic patients whose panic attacks last for several hours, an "as needed" approach may be the exception to this proscription. Average doses of alprazolam in panic disorder patients are 2 to 8 mg/day, with other benzodiazepines at commensurate levels. Studies show that gradual taper of benzodiazepines after several months of treatment resulted in almost universal withdrawal symptoms. A significant number of patients were unable to discontinue treatment. This is in contrast to antidepressants. In one study, only 18% of patients were able to discontinue alprazolam, whereas 82% were able to stop imipramine.

Cognitive behavioral treatment has been shown to be very helpful for panic disorder, especially with intermediate term treatment (18 sessions over six months) *vs* shorter term treatment, and especially in the hands of a skilled cognitive therapist. Exposure therapy has been shown to be helpful for concomitant agoraphobia, as well as other phobias, if present. At least two studies, however, have shown fluvoxamine superior to cognitive therapy in the treatment of panic disorder. Current practice would be to start with low dose SSRI and gradually titrate up to an effective dose. Severely anxious patients may be given benzodiazepines concurrently until antidepressant efficacy has been achieved, then tapered. Netazadone, imipramine or clomipramine, and pheuelzine, in that order would be reasonable alternatives if two or three SSRRs are either ineffective of not tolerated. The newer antidepressants (SSRRs and nefazadone) are better tolerated than the older ones (tricyclics and MAOIs), and are much safer. Cognitive behavioral therapy conducted simultaneously with pharmacotherapy will usually improve efficacy.

Successful treatment of panic disorder can lead to a 90% decrease in medical treatment costs and improved quality of patients' personal and professional lives.

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Treatment Update in Geriatric Psychiatry

MAJOR depression in older persons is distinguished by early- and late-onset. Early-onset depressions first occur earlier in life and tend to recur into late life. Late-onset major depression occurs for the first time after about age 60. In older persons, late-onset depression tends to be more chronic, to have either a short-lived or a partial treatment response to antidepressant medication, and to be more related to suicide than recurrence of early-onset depression. Two new findings add dimension to these observations: 1) a substantial proportion of late-onset depressions tend to foreshadow the development of a dementia such as Alzheimer's disease or vascular dementia; 2) the evolution of the concept of vascular depression. Despite the type of depression, it still develops within the context of life stress and lack of social support. The 1997 update on the 1991 NIH Consensus Development Conference on the Diagnosis and Treatment of Depression in Late Life further described the high degree of medical comorbidity and disability as well as the impact of depression on health services and resource use.

With the advent of structural MRI, subtle vascular changes in the brains of depressed older persons can be evaluated. Patients with late-onset depression tend to have hyperintense signals on T2 weighted MRI images in subcortical white matter, basal ganglia, and caudate and putamen nuclei. Small lesions (5 mm) in the left frontal lobes seem more closely associated with depression while larger left subcortical lesions of stroke patients seem related to poststroke depression.

Although the concept of vascular depression requires further clarification, its relationship to ischemic vascular changes in the brain, and with vascular disease risk factors such as diabetes, hypertension, high cholesterol or lipid levels, as well as coronary artery disease and hypothyroidism seems rather consistent. Clinically defined vascular depression patients tend to have greater cognitive impairments (in verbal fluency and naming), functional disabilities, and psychomotor retardation, and less agitation, guilt feelings, and insight than patients with nonvascular related depression.

With respect to depression in older persons, it has been recently recognized that older patients may not quite fulfill clinical criteria for major depression, having instead "minor" or "subsyndromal" depressions, but with clinical courses and responses to medication similar to that of major depression. These patients are as responsive to treatment with a serotonin-selective reuptake inhibitor such as fluoxetine as are patients with major depression, and also tend to relapse at a similar 50% rate when medication is discontinued.

The recent availability of atypical or unconventional neuroleptic medications such as risperidone (Risperidal), olanzepine (Zyprexa), and quetiapine (Seroquel) promises to increase the safety and effectiveness of treating older patients with either late-onset delusional disorders, or with behavioral complications of Alzheimer's disease and other dementias. Over 70% of patients with Alzheimer's disease develop behavioral problems such as delusions, agitation, and aggression that require psychotherapeutic medication. In the past, typical or conventional neuroleptics such as haloperidol or chloropromazine have been used but have important side effects, especially extrapyramidal motor signs and symptoms and tardive dyskinesia. The atypical neuroleptics are characterized by serotoninergic antagonism. Although they are different from each other the atypical neuroleptics are better tolerated than are conventional neoroleptics.

By the end of 1998, physicians should have a choice of four different cholinesterase inhibitors for the treatment of Alzheimer's disease. A substantial proportion of patients with Alzheimer's disease have improved cognition and improved activities of daily living with these medications. Unfortunately, although the drugs appear to improve symptoms, they do not seem to alter the course of the illness. There is new but uncontrolled evidence that cholinesterase inhibitors might also mitigate the emergence of some behavioral symptoms of the illness, including delusions, and may also be useful for patients with severe cognitive impairment.

Last year, the results of a randomized controlled trial indicated the potential efficacy of vitamin E and/or selegiline (Eldepryl) in altering the symptomatic course of Alzheimer's disease. Patients on either of the medications alone or in combination remained in the community and avoided nursing home placement about five to seven months longer than those on placebo. Although there was less deterioration of activities of daily living, there was no change in cognitive function, suggesting that it might be possible to change some elements of the illness without affecting the core cognitive clinical features.

Suggestions have been made that estrogen replacement therapy or anti-inflammatory therapy may delay the onset of Alzheimer's disease, because estrogen is neurotrophic to cholinergic neurons and inflammatory processes attend the progressive neurodegeneration. Although observational studies have supported this, there have yet to be adequate randomized clinical trials. Therefore, these approaches remain reasonable but unproven.

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The New Antipsychotic Compounds: Is a Clinical Choice Algorithm Possible?

MOST drug trials for schizophrenics have used conventional antipsychotics in the control treatment-arm of the experiment and have tended to involve narrowly defined, homogeneous schizophrenia subject populations. The newer antipsychotic medications (including clozapine) all have lower extrapyramidal toxicity than their conventional counterparts. The clinical groups, therefore, that have sensitivity to neurotoxic side effects (ie, first break subjects, children, older patients, nonschizophrenic conditions) should derive the greatest benefit from this characteristic, but few studies address these groups. It is therefore not possible to make direct comparisons of effectiveness or toxicity among the various newer medications, particularly for the more "normal" clinical population, but some conclusions can be drawn, and a few predictions made.

Among the available novel agents, clozapine and quetiapine possess the lowest extrapyramidal toxicity, followed closely by olanzapine and then risperidone. When extrapyramidal toxicity dominates the clinical picture, clozapine or quetiapine should be the first choice. Other toxicities associated with clozapine, (blood dyscrasias, seizures, sedation, cardiotoxicity, etc.), however, prevent its easy clinical use, even in cases of severe acute extrapyramidal toxicity.

The newer agents also differ from conventional compounds along endocrinologic lines. Clozapine and quetiapine do not elevate prolactin, and olanzapine generally induces only a mild, and usually transient, prolactin elevation. Risperidone, on the other hand, elevates prolactin at least as much or more than its conventional counterparts. In clinical circumstances where prolactin elevation is of clinical concern, as in young or adolescent females, or patients with clinical intolerance of hyper pro-lactinemia—amenorrhea, galactorrhea, gynecomastia, testicular atrophy, erectile incompetence—clozapine, quetiapine, or olanzapine should be used. Again however, because of the predominance of other toxicities with clozapine, olanzapine and quetiapine would be superior first choices. Other toxicities that are of clinical significance and do vary among this class include sedation, weight gain, and cardiovascular toxicity. Sedation is most severe with clozapine, and is generally the titration-limiting characteristic of this compound. Olanzapine has somewhat more sedative potential than either risperidone or quetiapine but substantially less than clozapine.

Weight gain should be anticipated with most of the new compounds. Forty percent of patients treated with atypical drugs will experience a greater than 10% weight gain. Measures to avoid weight gain are consistently more effective than those employed to induce weight loss. Clozapine and olanzapine seem to stimulate more weight gain than risperidone and quetiapine. All of these compounds increase weight more than the high potency conventional medications.

Cardiovascular toxicity has become a clinical concern because sertindole has been noted to produce more QT prolongation than conventional medications. Although a precise rank ordering of the risk of inducing ventricular arrhythmias is not known at this time, clozapine seems to have somewhat more potential than any of the other three compounds. Orthostatic hypotension with reflex tachycardia is the other major cardiovascular toxicity induced by these drugs. Here again, clozapine is the most difficult agent, followed distantly by the other three compounds.

Quetiapine's toxic profile, while favorable in most respects, contains a theoretical increased risk of eye complications, since its use in certain animal models results in the development of cataracts. This animal toxicity prompted the manufacturer and the FDA to advise slit lamp examinations before and during quetiapine treatment. Because the time course to the development of clinically significant cataracts is very slow, it is not our clinical habit to obtain a slit lamp examination before treatment. Instead, we perform routine clinical ophthalmoscopy before treatment (as we do on all patients) and refer only chronically treated subjects for ophthalmologic (or optometric) consultation. This way, only those subjects who are successfully treated with quetiapine, will have to undergo these more extensive, and expensive examinations.

On the other side of the clinical equation lies the question of relative efficacies among these compounds. For individuals who are resistant to conventional antipsychotic medication, such as haloperidol, clozapine is the most powerful medication. Clozapine also appears remarkably better than conventional medications in moderately refractory individuals. Among the other three compounds, only risperidone has shown therapeutic power superior to conventional medications in such groups. In treatment-responsive groups, both risperidone and olanzapine (but not quetiapine) appear superior to conventional drugs. A few studies have compared risperidone to olanzapine. These data suggest similar effectiveness, but, as mentioned above, somewhat different side effects.

In summary, these newer antipsychotic compounds, while clearly of lower extrapyramidal toxicity than their conventional counterparts, have other contraindications. The patients' specific clinical scenario must guide the clinician in choosing among these drugs. While clozapine is more toxic than the other three compounds, it is also the most powerful antipsychotic treatment available. Thus, when toxicity concerns predominate, clozapine will be a last resort, but when inefficacy is preeminent, clozapine should be tried earlier. Among the other three compounds, quetiapine in general is least toxic, but with the available data, also appears least effective. Choosing between risperidone and olanzapine is usually a choice between different toxicities, as they are equally effective. Olanzapine has more sedation, weight gain, and hepatotoxicity, and is more expensive, while risperidone has greater extrapyramidal and endocrinologic toxicity. Future studies should help delineate differences amongst the atypical drugs, allowing clinicians to better assign priority for use of the drugs in various clinical circumstances.

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Trovafloxacin: Fourth Generation Fluoroquinolone

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Introduction

THE fluoroquinolones are an important family of antimicrobials with a broad spectrum of activity, favorable pharmacokinetic and pharmacodynamic properties, and excellent tolerability. Despite the efficacy of these agents for serious gram-negative infections, the most widely-used of these agents, ciprofloxacin and ofloxacin, have limited activity against streptococci and anaerobes. The increasing resistance of strains of bacteria to currently available antimicrobials has spurred the development of more potent, "advanced generation" fluoroquinolones with expanded antimicrobial activity. Trovafloxacin (Trovan™, Pfizer) is a new fluoroquinolone with expanded activity against both gram-positive organisms and anaerobic bacteria. The enhanced antibacterial activity and improved pharmacokinetic properties (ie, pharmacodynamic profile) of trovafloxacin present the clinician with new treatment options.

Pharmacokinetics

Trovafloxacin has an excellent pharmacokinetic profile that compares favorably with other, recently-released fluoroquinolones and offers certain advantages over the earlier generation quinolones (Table 1).[1-3] Trovafloxacin has increased bioavailability compared to ciprofloxacin (90% *vs* 70%) and is not altered by the concomitant intake of food.[4] Trovafloxacin is rapidly absorbed after an oral dose and achieves linear, dose-related serum levels. The long serum half-life (approximately 10 hours) allows for once-daily dosing. Alatrofloxacin mesylate, the IV formulation, is the prodrug of trovafloxacin mesylate and is rapidly converted *in vivo* to trovafloxacin after IV administration. Trovafloxacin is partially metabolized in the liver through phase II conjugation (glucuronidation, N-acetylation, and N-sulfoconjugation); an inactive metabolite is eliminated in the urine. Approximately 50% of an administered dose is excreted unchanged (43% in the feces and 6% in the urine). Dosage adjustments are not necessary for older patients or for patients with renal failure or mild to moderate hepatic dysfunction.[5]

Trovafloxacin is widely distributed throughout the body and penetrates into most tissues at concentrations that equal or exceed concentrations observed in serum. Concentrations achieved in lung tissue, bronchial fluid, muscle, bone, gynecologic tissue, and prostatic tissue are sufficient for the treatment of infections at these sites.

Trovafloxacin has demonstrated inflammation-independent penetration into cerebrospinal fluid (CSF). This property is important in the treatment and prevention of relapse from meningitis once the initial meningeal inflammation has decreased. In one study, CSF was obtained during diagnostic procedures in 37 children following IV

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infusion of alatrofloxacin 180 mg/m^2 over one hour; another 11 infants received IV alatrofloxacin 5 mg/kg. Serum and CSF concentrations of trovafloxacin were determined in samples obtained between 2 and 24 hours after the start of the alatrofloxacin infusion. Trovafloxacin concentrations in CSF rose rapidly to levels more than 10 times greater than the MIC$_{90}$ of *S. pneumoniae*. Overall, the CSF:serum ratio for trovafloxacin was 0.22 to 0.28, indicating an approximate 20% to 30% CSF penetration.[6]

Safety Profile

As a class of antimicrobials, fluoroquinolones are well-tolerated at various doses. The most commonly reported adverse events associated with trovafloxacin during clinical trials were dizziness and lightheadedness (200 mg oral, 11%), nausea (200 mg oral, 8%), and headache (200 mg oral or IV, 5%). The dizziness/lightheadedness was generally mild, primarily associated with the first dose and resolved within several hours after a dose. Both the dizziness and the nausea can be minimized by giving the drug with food. It is not known whether the central nervous system side effects of trovafloxacin will be a clinical management problem. Trovafloxacin has a low phototoxic potential; treatment-related phototoxicity occurred in less than 0.03% of patients in clinical trials. In contrast, among patients treated with sparfloxacin in U.S. phase III clinical trials, the incidence of photosensitivity was 7.9%. Although cartilage toxicity has been observed in animal studies with other quinolones, no such articular damage has been found to date with trovafloxacin.[7] The perceived toxicity to developing bones has heretofore limited the use of the quinolones in children; therefore, the lack of this toxicity in trovafloxacin is potentially important in developing new treatments for pediatric infections. Because of its high CSF penetration, trovafloxacin is a potentially important, new option in the treatment of penicillin-resistant *S. pneumoniae* meningitis in children.

Drug-drug interactions with the fluoroquinolones fall into two distinct categories: interactions involving the gastrointestinal tract and those involving cytochrome P450 metabolism.[8] Like other fluoroquinolones, concomitant administration of oral trovafloxacin with magnesium or aluminum-containing antacids, iron supplements or sucralfate causes a substantial decrease in bioavailability. This effect can be avoided by administering the drug two hours before or after the antacid, iron or sucralfate.[9-10] Although trovafloxacin is extensively metabolized in the liver, the metabolic pathway is primarily through glucuronidation instead of oxidation. Trovafloxacin does not have clinically significant cytochrome P450 drug interactions. Dose adjustments are not necessary with the concomitant administration of theophylline, digoxin, or warfarin.[11–14]

Pharmacodynamics

Pharmacodynamic analysis is an integration of phamacokinetic and microbiological data to optimize drug therapy and improve clinical outcomes. The most common marker of microbiological activity is the minimum inhibitory concentration (MIC). Pharmacokinetic factors that relate to antimicrobial effectiveness are drug concentration and duration of exposure at the binding site. One way of expressing this pharmacokinetic relationship is the area under the serum concentration time curve (AUC), the product of peak serum concentration (Cp), and time. Fluoroquinolones, like aminoglycosides, exhibit concentration-dependent killing of bacteria; the higher the drug concentration at the binding site, the more rapidly the organism is killed. If the peak serum concentration relative to the MIC is high ($Cp/MIC \geq 10$), bacterial killing is very rapid and the duration of exposure contributes little to the killing process. When a Cp/MIC ratio of 10 or more cannot be achieved, bacterial killing is not optimized and the time element in the AUC/MIC relationship cannot be ignored. This situation occurs with fluoroquinolones in

Table 1.—Pharmacokinetic Comparison of Quinolones: Multiple Dose[1-5]

	Ciprofloxacin 750 mg	**Sparfloxacin 200 mg**	**Levofloxacin 500 mg**	**Trovafloxacin 300 mg**
Bioavailability	70%	92%	99%	90%
C_{max} (μg/mL)	4.3	1.1	5.1	4.4
T_{max} (hr)	1-2	3-6	1-2	1-2
$t_{1/2}$ (hr)	4	20	6-8	9-10
AUC_{0-24} (mg•hr/L)	40	19	48	46

relation to certain bacteria because high-serum drug concentrations can cause CNS toxicity. Under this circumstance, the AUC/MIC ratio is the pharmacodynamic parameter for the fluoroquinolones that correlates best to clinical outcome.

The pharmacodynamic profiles of trovafloxacin, ciprofloxacin, sparfloxacin, and levofloxacin are presented in Table 2.[15] Research relating clinical outcomes to pharmacodynamic parameters suggests that an AUC/MIC ratio greater than 125 is acceptable to treat a gram-negative infection; an AUC/MIC greater than 50 is adequate to treat a gram-positive infection.[16] Because of the inherent susceptibility of *Escherichia coli* to all but sparfloxacin, the Cp/MIC$_{90}$ ratio exceeds 100 for ciprofloxacin, levofloxacin, and trovafloxacin; the AUC/MIC ratio is far above that needed for an optimal clinical response. Against *Ps. aeruginosa*, however, the pharmacodynamic data suggest that none of these fluoroquinolones would be associated with high success rates when used as monotherapy for extrarenal infections; therefore, treatment should include a second agent.[17–19] Against *S. pneumoniae*, only trovafloxacin appears to have the required Cp/MIC$_{90}$ ratio of at least 10.[20–22]

The key difference between these agents is reflected in their pharmacodynamic profiles against *B. fragilis*, an anaerobe susceptible to trovafloxacin on the basis of the MIC$_{90}$. Trovafloxacin has an AUC/MIC ratio approaching that of metronidazole, the gold standard for treatment of susceptible anaerobes. Likewise, the Cp/MIC$_{90}$ ratio for a 300 mg dose of trovafloxacin given once a day exceeds that for a 500 mg dose of metronidazole given every six hours.[23–24]

Clinical and Microbiological Efficacy

The fluoroquinolones are used extensively to treat a broad range of gram-negative infections. The class weakness has historically been lack of coverage for gram-positive and anaerobic bacteria. Trovafloxacin's micro-

Table 2.—Quinolone Pharmacodynamics Against Organism MIC$_{90}$[15–20]

Organism	Drug	Dose	Cp/MIC$_{90}$	AUC/MIC
Escherichia coli				
	Ciprofloxacin	750 mg q12h	133	1,133
	Sparfloxacin	200 mg qd	18	317
	Levofloxacin	500 mg qd	110	833
	Trovafloxacin	300 mg qd	145	1,200
Pseudomonas aeruginosa				
	Ciprofloxacin	750 mg q12h	8.0	68
	Sparfloxacin	200 mg qd	0.6	10
	Levofloxacin	500 mg qd	1.7	13
	Trovafloxacin	300 mg qd	2.2	18
Streptococcus pneumoniae				
	Ciprofloxacin	750 mg q12h	2	17
	Sparfloxacin	200 mg qd	4	76
	Levofloxacin	500 mg qd	7	53
	Trovafloxacin	200 mg qd	12	96
Methicillin-sensitive Staphylococcus aureus				
	Ciprofloxacin	750 mg q12h	4	34
	Sparfloxacin	200 mg qd	9	152
	Levofloxacin	500 mg qd	26	212
	Trovafloxacin	200 mg qd	48	400
Bacteroides fragilis				
	Ciprofloxacin	750 mg q12h	0.2	3
	Trovafloxacin	300 mg qd	9	72
	Metronidazole	500 mg q12h	3	50
	Metronidazole	500 mg q6h	6	100

Cp Peak serum concentration

biological activity against typical gram-negative organisms is equivalent to that of ciprofloxacin and significantly better than ciprofloxacin for several difficult-to-treat pathogens such as *Burkholderia cepacia* (4 μg/mL), *Stentrophomonas maltophilia* (1 μg/mL), and *Acinobacter baumannii* (0.5 μg/mL). Trovafloxacin's advantage compared to the early generation quinolones is its expanded activity against both gram-positive and anaerobic pathogens. *In vitro*, trovafloxacin is equally active against both penicillin-susceptible and penicillin-resistant strains of *S. pneumoniae*. In an *in vitro* study of 202 pediatric isolates of *S. pneumoniae*, Thomson and colleagues found that trovafloxacin inhibited all isolates at a concentration of 0.25 μg/mL, 8 to 16-fold more potent than ciprofloxacin or ofloxacin.[20] In a comparative *in vitro* study of trovafloxacin to six antimicrobials using 489 clinical anaerobic isolates (including *B. fragilis, C. perfringens, Prevotella* spp., *Fusobacterium* spp., and *Peptostreptococci*), the overall MIC_{90} of trovafloxacin was 1.0 μg/mL; greater than 99% of all strains were susceptible to trovafloxacin at the breakpoint of 2.0 μg/mL or less.[23] Clinical trials involving mixed aerobic-anaerobic infections have confirmed trovafloxacin's activity against clinically significant anaerobes.[25] Trovafloxacin has the potential to simplify the therapy of complicated intra-abdominal infections by providing coverage of gram-negative and anaerobic bacteria with one drug given once a day. In the past, these infections have typically been treated with at least two drugs.

Trovafloxacin has been studied in 37 phase II/III clinical trials at doses ranging from 100 mg to 300 mg administered once a day. Trovafloxacin has recently received Food and Drug Administration approval for 14 indications, the largest approval for an antimicrobial drug in the agency's history. Indications for the 300 mg IV dose include nosocomial pneumonia, complicated intra-abdominal infections, and gynecologic and pelvic infections. The availability of trovafloxacin in both parenteral and oral formulations facilitates the early switch to oral therapy. The 300 mg intravenous dose is followed by 200 mg orally when a switch to oral therapy is indicated. Indications for a single dose 200 mg IV or oral include surgical prophylaxis of elective colorectal surgery and surgical prophylaxis of elective abdominal or vaginal hysterectomy. Complicated skin infections, including diabetic foot infections, are treated at 200 mg IV or oral. Other indications for 100 mg oral trovafloxacin include acute exacerbations of chronic bronichitis, uncomplicated skin infections, and uncomplicated urinary tract infections; indications for 200 mg oral trovafloxacin include community-acquired pneumonia, acute sinusitis, mild to moderate pelvic inflammatory disease, and chronic bacterial prostatitis.[26]

Conclusion

Trovafloxacin is a new fluoroquinolone with excellent pharmacokinetic and antimicrobial properties. The ability to administer the drug once daily in either parenteral or oral form facilitates the early switch to oral therapy which is crucial to decreasing hospital length of stay. As with any new drug, the full adverse event profile will not be known until further clinical experience with the drug is observed. Trovafloxacin's efficacy against clinically important pathogens, such as anaerobes, gram-positive bacteria, and *S. pneumoniae*, in particular, make it an important addition to currently available antimicrobials.

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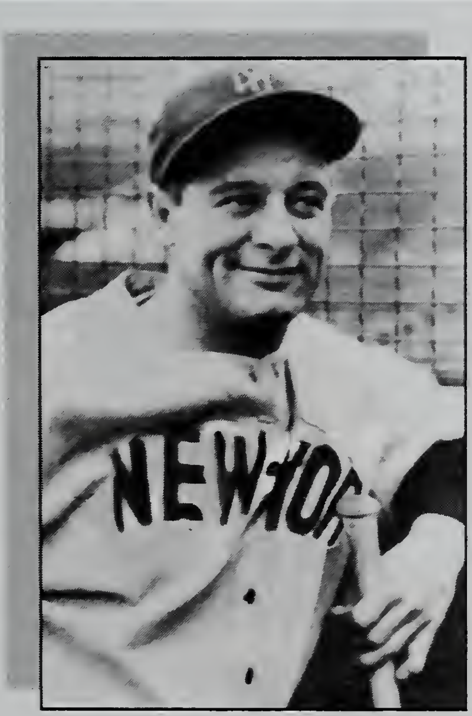

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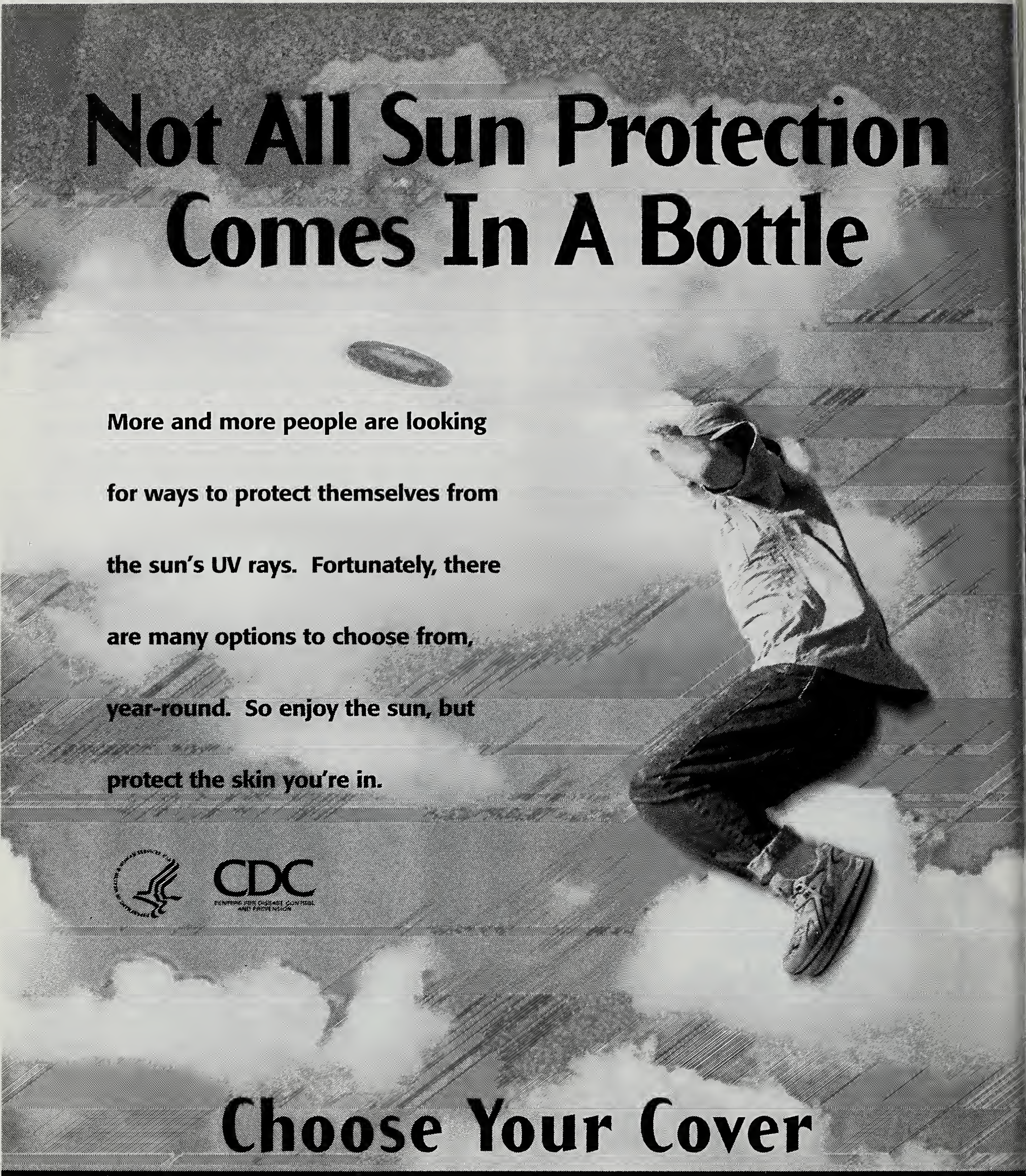

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Fenofibrate for Hypertriglyceridemia

Micronized fenofibrate *(Tricor*—Abbott), a fibric acid derivative structurally similar to clofibrate *(Atromid-S,* and others) and gemfibrozil *(Lopid,* and others), has been approved by the FDA for treatment of hypertriglyceridemia. Increased serum triglyceride concentrations have been associated with an increased risk of coronary heart disease (Jeppesen J, et al: *Circulation* 1998; 97:1029).

MECHANISM OF ACTION—Fibrates increase lipoprotein lipase activity and triglyceride clearance. They decrease hepatic secretion of very-low-density-lipoprotein (VLDL) cholesterol and release of fatty acids from adipose tissue. The reduction in VLDL levels leads to decreased transfer of cholesterol from high-density-lipoprotein (HDL) to VLDL, increasing serum HDL levels. The reduction in triglyceride concentrations shifts the sub-group pattern of low-density-lipoprotein (LDL) cholesterol to one that is less atherogenic (Shepherd J: *Atherosclerosis* 1995; 110 suppl:S55). These effects appear to be due to activation of peroxisome proliferator activated receptors (PPARs), nuclear hormone receptors that modify expression of several genes involved in lipoprotein metabolism (Schoonjans K, et al: *Curr Opin Lipidol* 1997; 8:159.

PHARMACOKINETICS—Fenofibrate has been available in a standard tablet formulation outside the U.S.A. for many years. The new micronized form is more rapidly and completely absorbed. A 67-mg micronized capsule is bioequivalent to a 100-mg nonmicronized tablet. Taking the capsules with food increases their absorption. Plasma concentrations reach a peak in six to eight hours. Fenofibrate is hydrolyzed in plasma to an active metabolite, which is conjugated in the liver and excreted mainly in urine, with a half-life of about 20 hours.

CLINICAL STUDIES—Clinical experience with micronized fenofibrate is largely unpublished, although many studies of the older tablet formulation are available. Comparative trials in patients with hypercholesterolemia and hypertriglyceridemia found that micronized fenofibrate 200 mg once daily decreased LDL cholesterol slightly less than 20 mg of simvastatin *(Zocor)* or pravastatin *(Pravachol),* but had a markedly greater effect on triglyceride levels, decreasing them by about 30% to 50%, and produced slightly greater increases (1% to 34%) in HDL cholesterol (Adkins JC, Faulds D: *Drugs* 1997; 54:615). In an open-label randomized study, 10 or 20 mg/day of atorvastatin *(Lipitor)* was less effective than nonmicronized fenofibrate 100 mg t.i.d. in lowering triglyceride levels or in raising HDL cholesterol, but more effective in lowering LDL cholesterol (Ooi TC, et al: *Arterioscler Thromb Vasc Biol* 1997; 17:1793). Few comparisons with gemfibrozil are available, but fenofibrate appears to have more favorable effects on LDL cholesterol levels (Jen S-L, et al: *Chin Med J* 1997; 59:217).

No data are available on the effects of fenofibrate on morbidity and mortality from coronary heart disease. Randomized trials with other fibrates have shown slower progression of coronary atherosclerosis and a decrease in the incidence of coronary events, but no effect on total mortality (Ericsson C-G, et al: *Lancet* 1996; 347:849; Frick MH, et al: *Circulation* 1997; 96:2137). Clofibrate reduced coronary events but increased total mortality because of an increase in malignant and gastrointestinal disease (Heady JA, et al: *Lancet* 1992; 340:1405).

ADVERSE EFFECTS—Rash and gastrointestinal symptoms have been the most common adverse effects of micronized fenofibrate. Increases in serum creatinine concentrations have been reported. As with other fibrates, cholelithiasis, hepatitis, and myositis can occur. In rodents, one to six times the maximum human dosage of fenofibrate increased the incidence of hepatic and pancreatic cancer.

DRUG INTERACTIONS—Like other fibrates, fenofibrate potentiates the effects of oral anticoagulants. Whether, like gemfibrozil and niacin, it could increase the risk of rhabdomyolysis when taken concurrently with a statin is unclear. If used with cholestyramine *(Questran,* and others) or colestipol *(Colestid),* fenofibrate should be taken one hour before or four to six hours after the resin. Fenofibrate may increase the nephrotoxicity of cyclosporine.

DOSAGE—*Tricor* is available in 67-mg capsules. The manufacturer recommends initial dosage of 67 mg once daily with a meal, increasing at four- to eight-week intervals, if necesssary, to a maximum of 201 mg once daily. The drug is contraindicated, according to the manufacturer, in patients with hepatic or severe renal impairment.

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SOME DRUGS FOR HYPERTRIGLYCERIDEMIA

Drug	**Daily Dosage**	**Cost***
Fenofibrate—*Tricor* (Abbott)	201 mg once	$ 61.88
Gemfibrozil—generic price	600 mg bid	10.80
Lopid (Parke-Davis)		81.75
Niacin immediate-release—generic	1000 mg tid	5.38
Niacor (Upsher-Smith)		50.71
extended-release—*Niaspan* (KOS)	2000 mg h.s.	66.60

*Cost to the pharmacist for 30 days' treatment based on wholesale price (AWP or HCFA) listings in *Drug Topics Red Book* 1998 and June *Update.*

CONCLUSION—Micronized fenofibrate taken once daily can lower elevated serum triglyceride concentrations, raise serum HDL cholesterol, and improve LDL holesterol. It is more convenient to take than gemfibrozil and may have more favorable effects on LDL cholesterol, but more direct comparisons are needed.

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Commentaries

Hold the Mayo

The word, Mayo, conveys different meanings to different people. A lunch counter cook hears it as a shorthand reference to mayonaisse; an Irishman knows it as the name of the meagerly populated western country, province of Connaught, in the Old Country, a name traced back to a pre-Norman monastery called Maio; but to physicians, it is the family name of three eminent surgeons—a father and two sons—who, toward the end of the 19th century, created a remarkable group practice in the small prairie town of Rochester, Minnesota.

William Worral Mayo, the senior founder of what eventually became the Mayo Clinic, was born in Manchester, England, and migrated to the United States at age 26. He taught school for a few years before apprenticing himself to an Indiana surgeon. When the Civil War needed physicians, he volunteered and was assigned as provost surgeon for southern Minnesota. And when Mayo returned to civilian life he remained in the area establishing his office in a small southern Minnesota community of Rochester.

Rochester was a prosperous agricultural community in Olmsted County but with no hospital. A devastating tornado in 1883, however, convinced its citizens to construct one. The institution, managed by the local Sisters of St. Francis, was called St. Mary's Hospital; and Mayo was its first surgeon. By 1890 he was joined by his two sons, William J. Mayo ["Dr. Will"] and Charles H. Mayo ["Dr. Charlie"] and the three maintained a productive and extremely busy surgical practice. By 1903 their informal alliance had been transformed into a cooperative practice as they incorporated radically new diagnostic instruments such as x-ray machines and recruited numerous physicians in other specialties to create one of the first group practices in this country.

The three Mayos were convinced, from the beginning, that continuing education was an indispensible element in preserving their clinical competency. Accordingly, they each devoted their yearly vacations to intensive medical review courses in one or another school of medicine, either in this country or abroad. This yearly ritual of going back to school became a requirement for the other physicians who had joined their group endeavor. And much of the fortune amassed by the Mayos was eventually invested in creating the Mayo Foundation, an internationally famous graduate medical school now affiliated with the University of Minnesota.

The Clinic prospered and by its 75th anniversary had treated over 3.5 million patients during the course of 25 million clinic consultations. The Clinic, moreover was more than a notable referral center; it also became the primary care facility for virtually the entire population of Olmsted County, some 100,000 men, women, and children.

One of the earliest physician-recruits to the Clinic was an internist named Henry S. Plummer. In addition to his clinical skills, Plummer had a genius for organizing information so that it might be readily and rapidly retrieved. Back in 1903 physicians generally kept their records in large ledger books with patient entries chronologically arranged. The ledger method was adequate when the physician wanted to review his labors for a particular day or consider his appointments for the next day; but to follow the clinical course of a single patient required the scanning of many pages. The ledger book worked reasonably well for the isolated physician in a rural community since most relevant information was stored in his memory. But by the turn of the century the nature of medical practice was undergoing rapid change. It became increasing common for an individual to be delivered by an obstetrician, treated for childhood diseases by a pediatrician, have his appendix removed by a surgeon, and then, later in life, have his heart disease cared for by an internist. If the ledger system had prevailed, there was no way that anyone might have easy access to a person's entire medical history.

Plummer realized that each new medical encounter by the patient might be better understood if it could be built upon the accumulated information gathered during all prior medical encounters, he then devised a novel new mechanism called the patient chart, a folder containing individual sheets summarizing each interaction with the medical profession, thus incorporating the patient's accumulated demographic, diagnostic, surgical, and therapeutic profile. He also assigned a unique lifetime number to each patient so that his/her folder might be easily filled—and retrieved—from a central repository called a Record Room.

Plummer was seeking something more than mere neatness and record-keeping efficiency. He knew that there were valuable clinical lessons to be learned in patient records, lessons not only for the physicians immediately involved, but for all physicians. The information lying fallow was useless unless it could be retrieved and somehow distilled. Accordingly, he devised a numeric system such that each diagnosis might be cross-indexed. His system, for example, allowed a clinical investigator to quickly retrieve all cases of thyroid cancer and determine, in retrospect, who in the general population had been the most vulnerable, what had been the range of outcomes, and which of the many treatments employed proved to be most beneficial. He perhaps anticipated the thoughts of Edna St. Vincent Millay:

> "Upon this gifted age, in its dark hour
> Rains from the sky a meteoric shower of facts.
> They lie unquestioned, uncombined,
> Wisdom enough to leach us of our ill
> Is daily spun, but there exists no loom
> To weave it into fabric."

These precious tons of patient records are housed in a single newly constructed repository connected to the clinic buildings by underground pneumatic tubes ferrying patient charts back and forth. The zealously guarded patient records are protected by a sophisticated fire suppression system and much is now electronically stored, as well.

In any three-year span, over 95% of the County population are being treated, or at least routinely examined, in the Clinic. Virtually every birth, every surgical procedure, every death, every autopsy in the County is recorded in the central files. These vast amounts of accumulating data permit searches [first by hand, then by mechanical sorting machinery, and now by electronic means] to uncover inapparent patterns of disease. For example, had the incidence of disease X changed? If so, in which age group? Which gender is at greater risk? Is the disease associated with any particular geographic site or occupation or therapy or lifestyle? Is it correlated with some other climatic or epidemiologic factor? Which form of treatment has worked best?

Under one roof in Rochester, Minnesota, is an irreplaceable collection of billions of pieces of clinical information waiting for epidemiologists to uncover causal relationships, undertake risk factor analyses, and plan therapeutic trials leading to a more rational practice of medicine. The three Mayos have indeed left a memorable and enduring heritage in the wheat fields of Minnesota.

Stanley M. Aronson, M.D.
Editor-in-Chief
Medicine and Health / Rhode Island

Why Congress Must Regulate Managed Care

Managed-care reform is needed at the federal level. Opponents of reform decry such efforts, claiming that health care should be subject to market forces. I understand those who favor free markets. But something so important as health care simply cannot be left to economic market forces alone. Unlike anything else in the market place, health care touches us all, often when we are most vulnerable or even helpless. Sooner or later, we are all patients.

Felix Rohatyn, the well-respected investment banker who engineered the bailout from near bankruptcy of New York City years ago, puts it best. "Although I believe the market place knows best most of the time," he said, "I am skeptical that it should always be the ultimate arbiter of economic action, and I am more than willing to interfere with it when it becomes a distorting rather than a benign influence."

Whether it be indifference, a lack of compassion, greed, a "what the large print giveth, the small print taketh away" mentality, or a failure to communicate, this much is clear: managed care has become a distorting influence, and a growing number of patients are not receiving care when they need it. Critics of managed-care reform tend to dismiss these unfortunate incidents as "anecdotal." That argument, advanced by HMO interests, reminds me of a Harry Truman remark a half century ago. He said that a recession is when your neighbor loses his job; a depression is when you lose your own job. Some insurers apparently think that a bad health outcome is an anecdote that only happens to somebody else.

Fortunately both political parties recognize how fraught with peril any indifference to this critical issue might be. Their constituents are demanding relief, and managed-care reform in the form of patients' rights legislation may well be the signature issue of the 1998 November elections.

Passage of the Dingell-Daschle legislation—The Patients' Bill of Rights (H.R. 3605 and S. 1890)—is crucial because patients are increasingly concerned about the quality of their medical care. They worry that they will not be able to see the specialists they need. They fear their health plan may deny payment for emergency service. They become enraged when their insurance plans sidestep their physicians and make medical decisions about their care. Above all, they are disturbed that, so far, Washington has been unwilling to act on their behalf.

Many states, including Connecticut, have indeed passed some patient protection laws. However, the fact is, 125 million Americans are unprotected because the federal Employee Retirement Insurance Security Act (ERISA) law preempts state laws that would have provided protection.

Employer objections are understandable. After all, they foot the bill in large measure for workers' health insurance, and these expenditures have escalated inexorably until the past few years. And it is only fair to acknowledge managed care's pluses. It has had a positive impact on wringing fat out of the system. It has helped everyone to examine costs more carefully. It has slowed down the rate of growth of rising health-care costs. But it is equally fair to weigh the negatives. Impediments to receiving care have become commonplace. Managed care has exacerbated the problem of the uninsured—41 million and growing. It has had a negative effect on medical education and clinical research. Dollars have dried up for these important endeavors and found themselves in the pockets of insiders and Wall Street investors. Managed-care organizations are growing larger through mergers and acquisitions, leaving caregivers little ability or leverage to reinstate adequate, reasonable fees. Legions of people believe that managed care's successes have been achieved at too high a cost—namely, a severe interference in the patient-doctor relationship, along with the rationing of our care by bureaucratic hassle and denial.

Managed-care organizations (MCOs) pride themselves on their "patient satisfaction" surveys which indicate a high approval rate. Without being cynical, who could be surprised that the satisfaction rate would be high? After all, only 6% or so of the population is sick and seeking care at any one time. Limiting the survey to them would evoke a far different response. Furthermore, the MCOs are not including in the surveys those patients who voted with their feet and left the health plan.

The managed-care organizations desperately want to establish credibility and to win favor with the public, but many of us wind up in HMOs by coercion, not by choice. For example, half of those Americans who have employer-based coverage have no choice of health plan. Another third can choose from only two plans, while only one-sixth can choose from more than two plans.

If HMOs want to connect with the public and show patients that they really care about their medical treatment, a good start would be supporting a Patients' Bill of Rights. Most people in this country don't yet understand the term "Managed Care"; when they do, as they will in the next few years, the revolution now brewing will seem tame by comparison. As the old Fram oil filters ads used to proclaim, "Pay me now, or pay me more later."

Yes, managed care has helped to cut the fat out of our health-care system, but it has moved well beyond that target and is now cutting into bone and tissue. Patients are being hurt in the process. Whatever public poll one refers to, managed-care regulation is either the number one public concern or close to it. Patients and consumer groups want accessibility, affordability, and accountability from their health plans. They want an independent appeals process and more information about their health plans. Patients want their choice of doctor, and they want his or her medical judgment to prevail. They want their personal and sensitive health data to be kept confidential. They also want an end to any physician "gag" policies, and they support a "prudent layperson's" definition for access to emergency services. (One survey indicates that "almost two in five Americans have been inside an emergency room in the past year.") And patients do want the right to sue a health plan if they are injured because necessary or appropriate care was denied or delayed.

Managed-care organizations protest that there is no need for regulation—let market forces determine what happens, they insist. The public does not agree with that assessment. A recent *Wall Street Journal*/NBC News poll found that only 23% of respondents believe HMOs "improve the health system," and 40% said "they make it worse." In that same poll, 86% say HMOs and other managed-care plans are more concerned with holding down costs than with providing good care. Any way you look at it, this is catastrophic news for HMOs and their supporters.

Perhaps the most significant finding of all in the poll, however, is a hypothetical election involving two political candidates. One supports tougher regulations to protect consumers from unfair treatment from HMOs, and the other says that additional government regulation will increase the size of government and raise the cost of health insurance. The result? The first candidate got 69% of the votes; the second received only 18%. Although it was only a hypothetical vote, local, state, and national candidates for public office might be wise to pay attention.

Wall Street influence may be good for the economy, but it is not necessarily good for patient care. Writing in the *New York Times*, Joseph Nocera points out: "The imperative that Wall Street demands of hot growth companies—that profits increase by eye-popping amounts year after year—doesn't quite jibe with the business of delivering first-rate health care to the public." Anything "eye-popping" is bound to come directly from patient care—at the expense of sick people and their caregivers—and go directly into the pockets of those investors who view the nation's patients strictly as just another commodity, either to yield a profit, or to be sold short.

Can we afford unregulated managed care much longer?

Timothy B. Norbeck
Executive Director
Connecticut State Medical Society
Printed in the Hartford Courant, 13 July 1998

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50 Years Ago
From *The Connecticut State Medical Journal*
August 1948

An "Index of Curative Skill"

"To become an able and successful man in any profession, three things are necessary, nature, study, and practice."

Henry Ward Beecher

No doubt many men, some obscure, others ultimately prominent, have undertaken the study of medicine and have abandoned it because they became more vitally interested in some other pursuit. Very often such men have wandered into allied fields of endeavor. Thomas Henry Huxley, the biologist, comes to mind as an example, for he as a medical student of nineteen described the layer of cells about the root-sheath of hair follicle which has since borne his name. Medicine must be a fascinating study even to those who abandon it, and we recently picked up an old book which illustrates what a profound impression it may leave on the mind of a contemplative observer: "Memories of My Life" by Francis Galton. The author, the grandson of Dr. Erasmus Darwin and the nephew of Charles Darwin, might be described as "the father of Eugenics," for after abandoning medicine one of his outstanding interests was heredity. As his book shows, his medical experiences made a profound impression on his mind, and in describing his hospital life he makes, among others, the following statement: "the opinions held by the students about the several physicians and surgeons were curiously guided by a mixture of loyalty and irreverance. There was no doubt of the fact that M., one of the doctors who never professed or had a claim to scientific acquirements, got his patients out of hospital more quickly than any of his colleagues." "It is to be wished that some 'index of curative skill' could be awarded to doctors, based on their respective hospital successes." "If it could be compiled truthfully, it would be an excellent guide to those who wanted a doctor but were doubtful whom to consult."

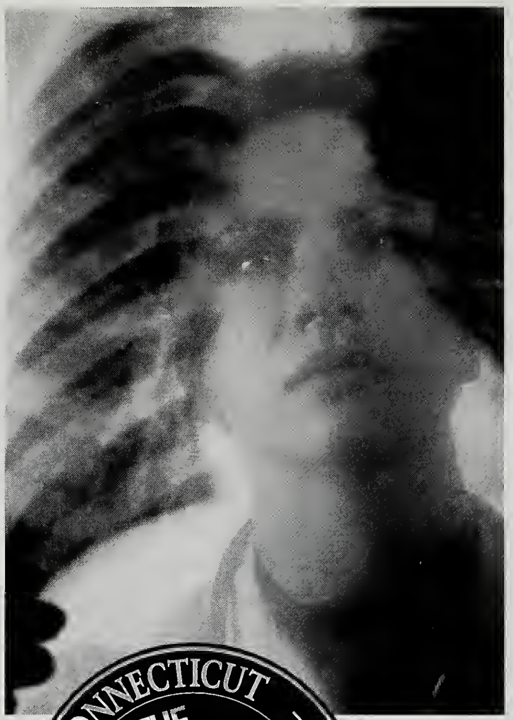
The idea that Galton suggests is interesting and stimulating, but one wonders how practical it is. We may note in the first place that Galton entered the Birmingham General Hospital as a house pupil in 1838, a period when the era of bleeding, purging and puking, while not perhaps in its heyday, was still in vogue. As for the successful doctor M., Galton records that his treatment "consisted of a strong purgative followed by a low diet, and a subsequent feeding up as soon as all fever had gone." That is not very different from the modern treatment of infections, minus specific therapy, for in the memory of many of us the "preliminary purge" was still, and no doubt is still, in use by many physicians.

So M. earned his index of curative skill, just as did the homeopaths, by demonstrating again what old Ambrose Paré had in mind when he recorded after so many of his case reports, "and I dressed him and God cured him." In brief, M., by leaving his well-purged patients to the tender mercies of Dame Nature and feeding them up during convalescence was more successful than his colleagues, many of whom were doubtless still wedded to the methods of Dr. Sangrado. He proved that the healing powers of nature, which the old-timers described as the "Vis medicatrix naturae," were infinitely superior to the drastic therapy of his day.

As to the feasability of ranking modern physicians in such an index as Galton proposed, we have our doubts. There have been, since Galton's time, not only immense advances in medical knowledge, but great progress in the classifying of competent doctors. Not that all doctors are, even now, equally successful in curing their patients. However, there are so many factors in therapeutic efficiency, including luck, good judgment, personality, knowledge, and skill, that we doubt that an attempt to fairly classify physicians according to their curative results would be very practical. We suspect that the matter of their efficiency had better be left in the hands of the Medical Schools, the State and Specialist Boards, the judgement of their peers and, above all, the good sense of the public, who in spite of their many vagaries, still tend, in the long run, to reach somewhere near the truth in estimating the capacity of physicians.

G.B.

Reprinted from the *Connecticut State Medical Journal*, August 1948.



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- Dermatologists
- Emergency Physicians
- Endocrinologists
- Family Physicians
- Gastroenterologists
- Geriatricians
- Gynecologists
- Hematologists
- Internists
- Nephrologists
- Neurologists
- Obstetricians
- Oncologists
- Ophthalmologists
- Orthopaedists
- Otolaryngologists
- Pathologists
- Pediatricians
- Physiatrists
- Psychiatrists
- Pulmonologists
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[*] *and D.O., Doctor of Osteopathic Medicine*

Breaking Down the Walls of Cynicism?

I was talking to a friend recently and we were bemoaning our many physician colleagues who seem almost clinically depressed by the changes facing our profession. "You know," I said, "We were all premeds once who would cut any throat and do anything that needed doing in order to get into medical school. Where is that fighting spirit now?" Of course, I was exaggerating but you recognize the stereotype of premeds.

Like any stereotype, though, there is an element of truth in it. Premedical students typically are highly motivated and willing to work and study long hours in order to gain admission to medical school. There is nothing wrong with that. But, the darker characteristic of premeds is the intense competitiveness. So competitive are they that they do not work well together and are often afraid to help one another. "If I help the next guy," goes the thinking, "Maybe he'll get accepted and I won't."

So, if physicians once had that competitive attitude, why do we seem so paralyzed when the government, the insurance companies, and the hospitals are threatening the way of life for which we worked so hard? Why are many of our colleagues acting so helpless and hopeless?

As I reflected on my offhand statement about premeds, I realized that many physicians do indeed still display many of the characteristics of premeds. Unfortunately, the characteristics one sees most are the negative ones with respect to how they interact with their peers.

Many physicians just cannot find it within themselves to work cooperatively with other physicians. They are proud of the "stubborn Yankee" mentality. They can't seem to trust other physicians to work in their best interest because those other physicians might somehow get an advantage over them. They are suspicious of the motives of even established, successful physician-led companies. "Organized medicine? Yesterday's news." "Ask a retired physician to step down from a leadership position to make way for emerging leaders? Oh, no. I can't be sure I would get the position, instead."

I think we can all recognize the cynical attitude the above statements represent. I am also sure we could all add more examples. Recognizing the cynicism is not the hard part. The task facing physicians in this state and nationwide is finding ways to break through the cynicism and to work together to preserve the practice of medicine and deliver the best care we can to our patients.

The current phenomenon in medical practice is the coalescing of physicians into large groups or hospital practices. How many physicians join these groups out of a genuine desire to have access to sophisticated medical information systems thereby allowing themselves to make informed, outcome based decisions about their practices and delivery of care? How many join the groups out of fear that they "have to do something?"

Large group practice does appear to be the mode in which most of us will be practicing within the next five to 10 years. Being joined in groups poses questions for us individually and collectively. Can we find it within ourselves to come together and work for the common good of the group? Are we going to be active, empowered members of a thriving group or are we going to be carping, resistant members of a struggling group? As groups, are we going to value the strength in numbers that interaction with our peers in the medical associations brings us? Or, are we going to aid and abet the managed-care companies by dividing up into warring fiefdoms?

It is time for all of us former premeds to make a choice. Are we going to allow cynicism to reign and let the forces of change defeat us? Are we are going to harness our competitiveness and work for the collective best interest? Which will it be?

Craig W. Czarsty, M.D.
President

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More on a Sustainable Medicine

ROBERT U. MASSEY, M.D.

> I am not so much concerned about the General Election....No; the vision is always solid and reliable. It is the reality that is often a fraud. —Gilbert Keith Chesterton.

SINCE last month when, I wrote about "A Sustainable Medicine" and Daniel Callahan's most recent book, *False Hopes: Why a Quest for Perfect Health Is a Recipe for Failure,* I have been turning his predictions, warnings, and conclusions over and over in my mind. You may recall that he began with a proposition that we all accept: continuing increase in the cost of health care as a percentage of the GNP is unsustainable. These rising costs, driven by demands for perfect health, freedom from all disease, discomforts, and lowness of spirits, freedom from aging, moroseness, and ultimately from death itself (did you know there is an American Academy of Anti-Aging Medicine?), cannot be sustained forever. Inflated by greed for profit and power, health-care costs must finally deny resources for all other social goods—education, art, literature, a reasonable life span, a sustainable environment, a place in the world market, and even national defense. As Lewis Thomas wrote somewhere, "All this concern about health is unhealthy." It is, in fact, more than that: it corrupts and distorts our lives.

I have spoken with friends about Callahan's thesis, mostly physicians and lawyers. He is quite right, they agreed, but there seems little anyone can do about it. "Are you going to tell an 85-year-old man that he can't have his sixth hip replacement?" asked a surgical colleague. "Just take all profit-making out of the system, and increase copayments until they hurt a little for all medical care—that will start the market moving in the right direction. And don't forget, most important of all: cover the 41 million presently uninsured—that will force some healthy decisions!"

As I think back over conversations like these, other themes have recurred. "We have a single-payer system now—Medicare—why not extend it to everybody?" Another one: "Except for those at or near twice the poverty line, we should all pay out of pocket for medical care, including hospitalization, up to 10% of our after-tax income; anything *appropriate* above that should be covered. Individuals or families would be quite free to purchase conventional health insurance, or establish tax-free medical savings accounts.

Most physicians, including me, know far too little about health economics to be of much help in these matters. Those of us who are survivors from an earlier day recall a time when hospital insurance, Blue Cross and other similar schemes, was all there was. Physician services then cost, allowing for inflation, about the same as they do today, but the options now are far greater. Surgery then meant an appendectomy or herniorrhaphy, not a heart-lung transplant. Most of us took care of our patients without anyone asking them whether or how they could pay. In my practice, by no means unusual, two thirds did pay sooner or later. Since they expected to pay out of pocket, most thought twice before incurring another debt—except when the kids were sick.

Callahan defines several characteristics of "steady-state medicine." "For example, ... it would feel no compulsion to rid the world of infertility." Another tougher message: "high-technology rescue medicine will be scarce for the elderly, limited for babies and children, and reduced for all other groups." Screening for low-risk cancers or heart disease "should be limited, done only when strong evidence exists of a significant benefit for many, not a few." For those over age 65 or 70, "the highest priority for medicine should become not to avert death but to enable people to live as comfortable and secure a life as possible."[1(256)] And for the dying, "[a] steady state medicine will educate its physicians to understand that the care of the dying is as much their responsibility as the care of those who can be cured.... Palliative care is an old art, and yet a new frontier as well."[1(258)]

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

In his book *The Limits of Medicine,* Edward S. Golub asks of medicine's goals:

> As a society do we want scientific medicine to prevent death indefinitely, to relieve all suffering, to take the responsibility for health and disease out of our hands altogether,...? A strong case can be made that the normal human life span is only slightly more than the biblical three score and ten. Has scientific medicine received a signal from society to roll back death indefinitely?[2]

I guess some think the answer to that is "yes," but I doubt it. As a society can we really do anything about the goals of medicine or the automotive industry or the world-wide web or sex on the internet? Lewis Thomas, in his essay "On Meddling" refers to Jay Forrester and his computer models of complex systems, "in which he makes clear that whatever you propose to do, based on common sense, will almost inevitably make matters worse rather than better.... Intervening is a way of causing trouble."[3(111)]

Medicine, in fact the whole health-care enterprise, has changed in unbelievable ways, for both better (50% of our medical students are women) and worse (hundreds, even thousands are now getting rich in the "health-care industry"), in the more than half century since I entered medical school. During the 50 years before that changes had been even more amazing. No one planned any of this, although politicians and others in power thought they were making a difference, designing the future, making everything better. Fifty years ago, smoking cigarets was as common as going to the movies. "More doctors smoke Camels than any other cigaret" was an ad in *Connecticut Medicine.* (June 1998). In the past decade the Soviet Union has collapsed, Germany is reunited, Johnson's Great Society is in shreds, smoking has become a punishable offense, we can clone sheep and mice, and we have a world-wide epidemic of a disease no one had heard of 18 years ago. With all our devotion to health as the ultimate concern we have more obesity than any nation on earth, more drug addiction, more violence, and cigars are fashionable again. No one planned any of this, or even predicted it with confidence, although many will claim they saw it all coming. It seems to me that history just happens, undoubtedly following the laws of our incredibly complex social systems which no one understands, least of all the academics and politicians. The poets and the novelists have had better insight, and generally are better prophets. Much of this was seen, "although through a glass darkly," by Alfred, Lord Tennyson, Jules Verne, H. G. Wells, Aldous Huxley, and a few others.

We will reach a sustainable medicine, or get close, because events, the market itself, will force us to it, but I doubt that we can plan it in all its details. We will muddle into it, just as we will surely muddle into a single-payer system for health insurance. Perhaps we can get our political masters to regulate the profitable medical care organizations to death, make them too expensive for industry to pay for, too unprofitable for insurance companies to mess with. Muddling is often best—that is what evolution does and it works. Nibble at the thing bit by bit. Physicians may even recover their vision of a Hippocratic medicine where profit taking has no business. And all the while in biomedical research laboratories all over the world we will be moving closer to Lewis Thomas's vision of high-technology medicine:

> The point to be made about this kind of technology—the real high technology of medicine—is that it comes as the result of genuine understanding of disease mechanisms, and when it becomes available, it is relatively inexpensive, relatively simple, and relatively easy to deliver.[4(35)]

Something else needs to happen, and it too will be unplanned. One cannot fail to sense, as this millenium closes up shop, a growing urge to find meanings, a quest for spiritual significance in a society that often appears to have lost its way. The manifestations of this quest are sometimes silly, but more often entirely serious. Something like this followed the Enlightenment at the end of the 18th century, but looking for history to repeat itself is a vain search. Nevertheless, in the course of rediscovering what we should really be about, we may shed some of our intense individuality with its hundreds of "rights," recover a compelling morality, and recognize that our democracy cannot be counted on to work for long unless we relearn that we are our brothers' keepers.

Then, by bits and pieces, and perhaps state by state, with no all encompassing central plan, sustainable medicine, like a sustainable environment, will fall into place simply because it must. Old G. K. Chesterton was right: The vision is solid and reliable! The present reality is the fraud!

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This Month's Reading in Review

TIMOTHY B. NORBECK

Under the headline, "What Happened to Patients' Rights in Health Care?," *Newsday* columnist Robert Reno writes: "I presume we are supposed to sit back and watch capitalism work its way as it does in all private industries.... Natural competitive tensions will weed out the weak players and leave some dead bodies as free markets work to make a more rational, efficient, cost-effective, choice-driven system.... The problem is, of course, that since we're dealing with health care—and not such successfully reconfigured industries as steel, automobiles, or railroads—some of the dead bodies will be real dead bodies."

Newsday (8 July 1998)

Speaking at the Florida Managed Care Institute's June annual convention, former Surgeon General C. Everett Koop said, "HMOs meant that a variety of bean counters has all crowded figuratively into the doctor's office." ... Calling HMOs "totalitarian forces," Koop said, "We need a system that delivers care that is medically necessary and appropriate, not the most profitable."

St. Petersburg Times (6 July 1998)

Paul Ellwood, one of the original developers of managed care "theory," said he is "disappointed ... with the system he helped create."... He said, "The idea was to have health care organizations compete on price and quality.... The form it took, driven by employers, is competition on price alone."

Time (13 July 1998)

Last year, more than 112,000 cases of Lyme disease were reported in the United States, nearly 17,000 of them in Connecticut.

Physicians Financial News (30 June 1998)

"Although the American Medical Association has long supported medical malpractice limits on pain and suffering awards, as well as medical savings accounts, we do not support their inclusion in any patient protection legislation. We will fight that battle on another day. We support the Dingell-Daschle bill because it addresses five objectives: information disclosure for patients, an independent appeals process, a method for holding health plans accountable for medical decision-making, a prudent-layperson definition for access to emergency services and termination of physician gag policies."

From a letter to the editor by
Randolph D. Smoak, M.D., Board Chairman
of the AMA. *New York Times* (1 July 1998)

People with Too Much Money: An April *Associated Press* report disclosed that, since 1961, Americans have sent the U.S. Treasury more than $56 million in voluntary contributions toward reducing the national debt.... Gifts are mostly checks for $15 or so, but one Minneapolis woman gives $3,000 a year, and in 1994, an anonymous patron sent in $20 million.

America Online (13 July 1998)

CNN's Bruce Morton reported that "Many voters feel the quality of health care is declining.... Right now, the focus is on managed care, or HMOs."... Democratic pollster Mark Mellman said, "People believe that the reason the quality of care has declined is fundamentally one reason, and that's greed."

Congress Daily/A.M. (10 July 1998)

Federal judges whose "hands are tied" by the Employee Retirement Income Security Act (ERISA) in cases where patients attempt to sue their health plans are calling on the federal government to reevaluate the law they say has "gone conspicuously awry."... ERISA was originally intended to prevent the "looting or squandering" of pension funds and to create "uniform federal standards...to encourage employers to provide benefits to workers."... However, the statute has in effect precluded any legal remedy for plaintiffs suing HMOs when a denial of care resulted in death or injury.... Federal judges presiding over such cases have declared that "modification of ERISA in light of questionable modern insurance practices must be the job of Congress, not the courts."

New York Times (11 July 1998)

Only in America: A man walked into a Circle-K (a convenience store similar to a 7-11), put a $20 bill on the counter and asked for change.... When the clerk opened the cash drawer, the man pulled a gun and asked for all the cash in the register, which the clerk promptly provided.... The man took the cash from the clerk and fled—leaving the $20 bill on the counter.... The total amount of cash he got from the drawer? Fifteen dollars.

Internet (13 July 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

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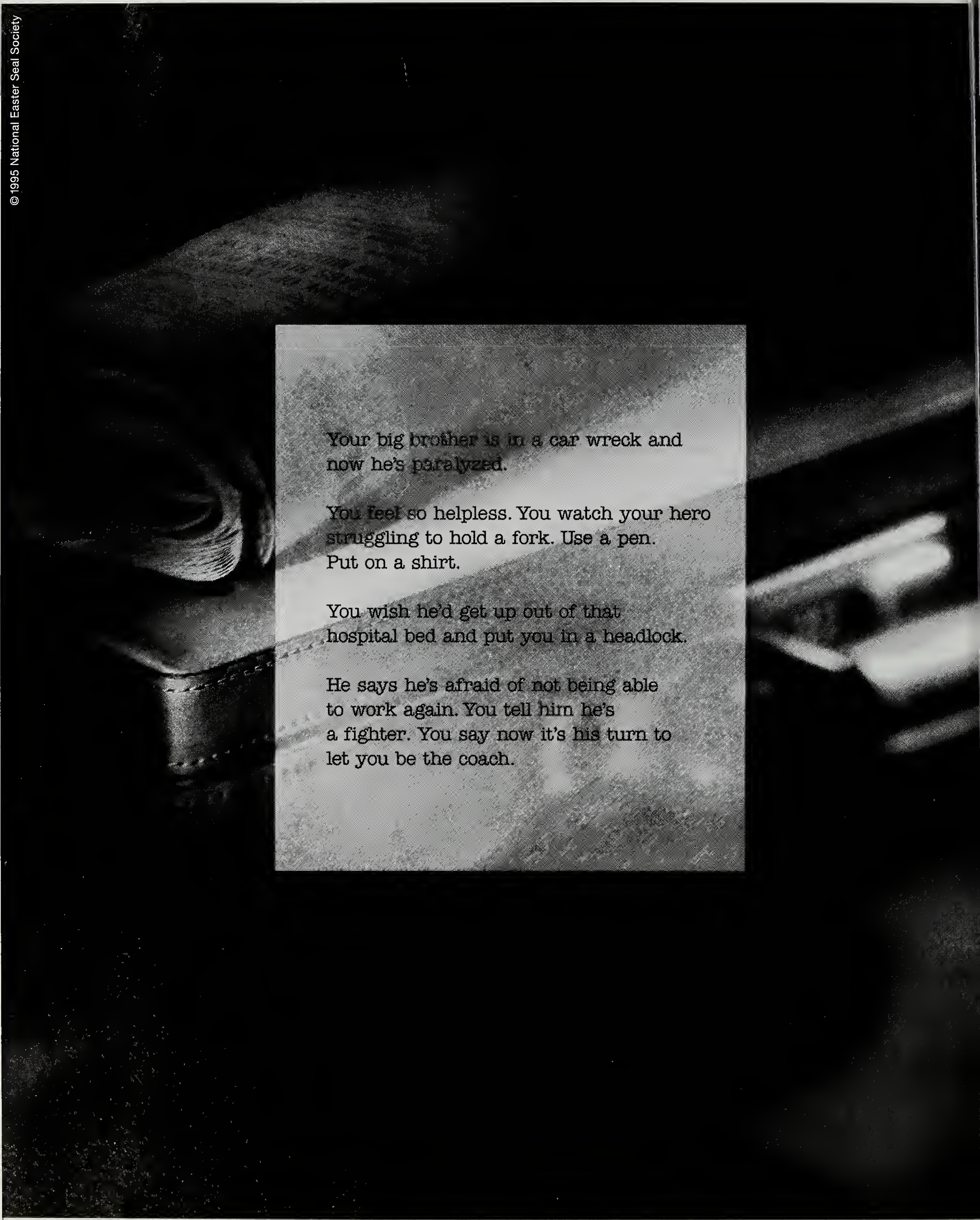

Your big brother is in a car wreck and now he's paralyzed.

You feel so helpless. You watch your hero struggling to hold a fork. Use a pen. Put on a shirt.

You wish he'd get up out of that hospital bed and put you in a headlock.

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

"Physician Assisted Living"

Letter to the Editor: One of the readers of our HUMAN LIFE News sent us sections from your December 1997 issue which focused on the "Physician Assisted Living" initiative. (*Conn Med* 1997; 61[12])

I was wondering if there had been any further movement on this? I was also wondering if a website had been established for this, as one of the articles hinted?

These topics concerning end-of-life care and pain management are of great interest to us in the Northwest, owing to our defeat of a physician-assisted suicide initiative in 1990, and the passage of a similar law in Oregon, our neighbor to the south.

Any information you could send us on the subject would be greatly appreciated. Or, if you could refer us to someone, or to a website, that might have some follow-up on your excellent journal issue on the hospice movement and PAL, it would be very helpful. In the last issue of our newspaper, we recounted the story of one family's difficulties in getting good treatment for a dying family member in the Seattle area. This has generated so much reaction—mainly of similar experiences by our readers—that I would like to keep the momentum going. We have a circulation of 57,000 of which some 500+ are physicians. So it would be great to show some positive alternatives to the rather depressing portrayal of our local health-care system.

Thank you for your consideration.

Elenor K. Schoen
Associate Editor
Human Life of Washington

"Neutrinos, the Mind and the Theory of Everything"

Letter to the Editor: Your "Neutrinos, the Mind and the Theory of Everything" pleasantly excites those of us whose heads are programmed like your own. A neutrino could pass through three trillion light years of lead without hitting anything. There's a lot of room out there. So why do we require a brain or any thinking machine to be compact like our own? An anthill is larger and could be said to have a community brain.

Why can't the universe be a large brain? We would say no if in addressing this concept we would arbitrarily exclude a thinking machine which requires more time than our own. A restriction like that cannot be justified.

We all know what time is but no one can define it. My dictionary does a poor job, goes around in circles. Everyone "knows" what consciousness is but it defies explanation. My dictionary, likewise, sneaks around in circles on that one too.

I had my hands on Dennet et al's *Consciousness Explained,* but now cannot find it in my library's computer. This is is no loss as they explain nothing of the sort. Roger Penrose in his *Shadows of the Mind* tries to explain consciousness as a quality derived from subtle structures in the brain. A failure in my way of thinking.

Someone said that a human being is an example of matter contemplating itself. Why restrict this to a 150 pound man bound up in skin? We could be the universe's microscope as it contemplates itself—and us—and everything.

An unborn baby, near term, can hardly be said to be processing much, if any, information and therefore could hardly be thought of as being conscious. Then, coming out into the world, abruptly, it handles lots of it. *Consciousness follows hand-in-hand.* I can't get it out of my head that consciousness and information processing are joined together at the hip. Inseparable.

A copper wire processes information. It remembers how many times it is bent, finally breaking. Who is to say that consciousness is an all-or-nothing? I, myself, have experienced partial consciousness in lecture halls, temporarily subsiding to near the level of a twitching copper wire.

Someone postulated that a computer could be made that would duplicate a human brain. Never mind that it would take a hundred thousand years and occupy a warehouse. The point is that in principle it could be done. Giving it sensors and feeding it problems, would it be conscious? My library's copy of *The Collected Works of John Keats* weighs three pounds and your correspondent is loath to plow through it to affirm he should be given credit for the idea that the universe is conscious and that we all just have one piece of it. The poet would surely say that that warehouse is conscious.

Awareness could be a *given,* philosophically akin to those of Euclid.

In a determined, mechanistic world we are all unconscious automitons savoring nothing, except in appearance.

Some mysteries may never be solved, such as, how a black cow yields white milk, or a white chicken produces brown eggs, or how a brown baby comes out of a white woman, or whence comes consciousness. I say enjoy the milk, savor the egg, love the baby, and wallow in the awareness that allows me to thrill with the song of the hermit thrush, to enjoy a hug, laugh at a good joke, and otherwise luxuriate in all the goodies around.

George Orwell had to participate in a hanging.... "He and we were a party of men walking together, seeing, hearing, feeling, understanding the same world; and in two minutes, with a sudden snap, one of us would be gone—one mind less, one world less."

Yes, George, we could be here to contemplate.

Fowler White, M.D.
Torrington

Be Not Afraid!

Letter to the Editor: A recent article in the New England Journal of Medicine revealed that only seven-tenths of one percent of our Medicare money would be saved if we were to institute a euthanasia ("mercy killing") program in the U.S. similar to that which is currently in vogue in the Netherlands.

I'm not at all discouraged! Once Medicare policy planners get their foot in the door with an initial "decriminalization" of physician assisted suicide, they will rapidly find ways to expand the applicable indications and criteria. Once that is done, through the dual miracles of public-private partnership and managed entrepreneurship, a new private company, Euthanacorp (probably a division of a large HMO), will emerge. It will set standards and criteria which we will be assured by recognized experts fall "well within the broad enabling framework of the decriminalizing legislation." With that, physician assisted suicide will easily and rapidly exceed one billion dollars in savings!

Once the $1 billion mark is reached of course, through the further miracle of managed competition, other companies will spring up and the market will rapidly expand. ("Work expands to fill the corporate treasuries available"—a variation on somebody's law). Before you know it, tens of billions of dollars will be saved in Medicare and Social Security payments each year! And the government will tell us they had nothing to do with it. Politicians—Republicans and Democrats alike—will crow about "the miracle of free markets!"

Seriously, does no one realize where our government is leading us? Towards Corporatism—a form of socialism wherein government utilizes private business to do its handiwork. It used to be called Fascism. Also National Socialism (abbr. Nazism). But we don't use those terms now. They don't reflect America's "diversity."

But those terms do tell the truth about where we are being led. By both the Administration, and the Congress. And the average American remains blissfully ignorant of what is going on in our country.

It's a pity, really. That old "cottage industry medicine" really used to care for people! Not any more.

Stephen R. Katz, M.D.
Fairfield
President-elect, CSMS

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From the Executive Director's Office

COUNCIL MEETING

Wednesday, 25 June 1998

Attendance

Present, in addition to the Chairman, Dr. Hollister, were Drs. Ahamed, Aleali, Beck, Bigos, Bobruff, Carolan, Conant, C. Czarsty, J. Czarsty, Deren, Eslami, Franklin, Katz, Keating, Lesnik, Montegut, Narayanan, Redmond, Sachs, Sadowski, Scarpa, Sosa, Timmerman, Van Linda, and Wetstone.

Also present were: Drs. Parke and Thompson, Mr. Norbeck, Ms. Lindquist, Mr. Brunell, Ms. Morelli, Ms. Schaffman, Ms. Norbeck, Mr. Staples (all CSMS staff), Mr. Thompson (FCMA staff), Ms. Debiase (NHCMA Staff), Mr. Fiorentino (HCMA staff), and Mr. Schuman (NLCMA, MCMA, WCMA, and TCMA counties staff).

Absent were: Drs. Brooks, Geary, Geist, Handelman, Herzog, Maloney, Schwartz, Sindwani, Tesoro, and Turner.

Organizational Meeting

The organizational meeting of the Council for 1998–99 was called to order by the president, Craig W. Czarsty, M.D. He welcomed the old and new councilors and asked them to introduce themselves. He then asked for nominations for chair and vice-chair of the Council for 1998–99. It was VOTED to elect Dickerman Hollister, M.D., Greenwich, chair, and Michael M. Deren, M.D., New London, vice-chair.

Reports of Related Organizations

CSMS-IPA: Dr. David Thompson, Jr., president of the CSMS-IPA, introduced the new executive director of the IPA, Mr. Ken Laline. He stated that now that there is an executive director, all items of business dealing with the IPA will be handled in a more orderly fashion and that he will be available to physicians seeking information. Mr. Laline presently will be working out of the CSMS office, but separate office space is planned, and as things progress, staff will be hired to handle the work load, much of which is currently being done by the M.D. Health Plan staff. A detailed report was distributed to bring the Council up to date on the activities of the IPA. Dr. Thompson highlighted some of the issues detailed in the report, one of the major issues being the negotiations for a new contract with the HMO providing a considerably larger percentage of premium to pay for health-care costs and provide services through the CSMS-IPA.

It was reported that 1998 is a transition year, and it will not be known until almost the end of the year how things will turn out with the complete integration of the PHS members into the organization. However, the ground work will have been set for 1999 with increased income, reduced costs for lab, hospital, nonphysician providers, and home care. The goal for 1999 is to return 100% of the withhold and look to increase fees.

Dr. Thompson responded to many questions that were raised. Following a lengthy discussion, it was VOTED that Dr. Thompson, with IPA staff, prepare a full report on some of the questions raised in time to be included with the agenda of the next council meeting. At that time questions can be asked and a decision made as to whether a fuller discussion is necessary.

CMIC: Dr. Ahamed reported that in his last report to the Council he mentioned that PIE Mutual Insurance Company of Ohio went bankrupt. It was reported that in Connecticut, the insurance commissioner allots a percentage of money to be given by all the insurance companies to a general fund, so that when companies go bankrupt, this fund would cover the loss. CMIC would only be responsible for medical liability companies that went bankrupt. This fund that CMIC is contributing to could be increased as time goes by, if companies that do not have sound financial basis are allowed to come into the state to do business. CMIC has discussed this issue with the insurance commissioner.

Dr. Keating reported that at the last Hartford County board meeting, the board unanimously endorsed CMIC as the preferred malpractice carrier for the Hartford County Medical Association physicians.

Following Dr. Ahamed's presentation, Dr. Craig Czarsty stated that perhaps it was time for strategic planning as to where the Connecticut State Medical Society is going. Dr. Czarsty provided a proposal from Harrison Coerver & Associates, management consultants, which was distributed to the members of the Council. The proposal includes a two-day seminar and would feature assessment of the present situation, objectives in priority sequence, and specific action plans for CSMS. A motion was made to engage Mr. Coerver to do a strategic planning session for CSMS. It was VOTED to refer the motion to the Fiscal Subcommittee for study and recommendation.

American Medical Accredition Program (AMAP)

Dr. Ahamed discussed the AMAP program, a comprehensive program developed by the AMA which measures and evaluates individual physicians against national standards, criteria, and peer performance in five areas: credentials, personal qualifications, environment of care, clinical performance, and patient care results. Dr. Ahamed noted that CMIC has the capability and mechanism to do certain aspects of the AMAP credentialing; the remaining credentialing components are a very expensive undertaking. He stated that in Connecticut AMAP could best be done in partnership with the AMA and CSMS, and that such a cooperative measure would be a good thing for the state's physicians.

As a result of Dr. Ahamed's report and the subsequent discussion, the Executive Director was requested to work with CMIC and AMAP to develop a proposal for implementing AMAP in Connecticut, for presentation and consideration at the 26 August Council meeting.

Report of the President

Dr. Czarsty reported on his attendance at the AMA meeting and stated that it was an upbeat meeting; the Sunbeam issue seemed to be put to rest. It was reported that Nancy W. Dickey, M.D., took office as president. Thomas Reardon, M.D., was elected president-elect, and AMA's new executive vice president is E. Ratcliffe Anderson, Jr., M.D. Dr. Dickey will be speaking at a Middlesex County Medical Association and Chamber of Commerce breakfast meeting on 24 November, and he asked the councilors to make a note of this date. Dr. Czarsty reported that he met a resident from Hartford Hospital, Willie Underwood, M.D., who expressed an interest in activating the CSMS Resident Physician Section, and a meeting is planned with him.

He informed the Council that Alfred Herzog, M.D., councilor from Hartford County, was elected speaker-elect of the Assembly of the American Psychiatric Association. Dr. Czarsty met with the Committee on Ethical and Judicial Affairs, which reviewed the draft of a document entitled "Conflict of Interest" that was mailed to the councilors. The document was revised at the committee meeting and was distributed to the council members for their review.

Dr Czarsty informed the Council that he planned to have a president's dinner with the president or president-elect and the executive director of each of the county associations to discuss items of common interest.

In response to questions raised about Physician Care of Connecticut and MedServ, Dr. Czarsty responded that Physician Care of Connecticut is in the middle of a stock offering that would close on July 18. At the present time, they have not raised enough funds to make escrow, and are in serious discussion with a large insurance company that does not have managed-care products in Connecticut to purchase a large volume of shares.

As to the questions about the MSO, he stated that once CSMS adopted a policy of conflict of interest, he would disclose that he does have a potential conflict of interest on the MSO issue. MedServ has been and continues to look into a variety of MSO services built on the MSO that Hartford County organized several years ago. Therefore, to relieve himself of the conflict of interest, Dr. Czarsty stated that he has recused himself from any discussion of MSOs at MedServ and would excuse himself from any discussion of the CSMS MSO.

Report of the Executive Director

Mr. Norbeck reported on the following items:

PARCA legislation (The Patient Access to Responsible Care Act) sponsored by the Georgia congressman and dentist, Charlie Norwood, is receiving wide publicity. His legislation would preempt ERISA and expose HMOs to medical malpractice lawsuits. Originally written, the bill would also have allowed such suits against employers. Sensitive to the many complaints from business, Congressman Norwood changed the legislation to reflect those concerns so that employers could not be sued unless they made the actual denial of coverage decision. Opponents of PARCA still misrepresent the legislation by scaring employers into believing that they will be sued as well as HMOs. Business groups are characterizing PARCA as a "trial lawyer's dream," but an employer's nightmare. The actuarial firm, Milliman & Robertson, has stated that PARCA would raise health insurance premiums nationwide by an average of 23%. U.S. Chamber of Commerce President and CEO, Tom Donohue, stated that if PARCA's liability provision becomes law, the Chamber would recommend that every business give their employees a check and get out of the health-care business. The AMA would like nothing better than to have this happen: that PARCA passes with the liability provision and that employers give employees a check so that they can purchase their own coverage. Most experts claim that there will be no federal managed-care reform this year, especially PARCA. They do not believe that corporate America will allow it.

Republican Health Task Force chair, Dennis Hastert of Illinois, held a press conference in Washington to announce the legislative framework agreed on by the task force. The language included the following items: anti-gag clause, information disclosure, confidentiality, emergency room coverage, medical savings accounts, tort reform including a $250,000 limit on pain and suffering and punitive damages, and external appeals process.

PARCA has language that could be interpreted to pay limited licensed practitioners the same as physicians for similar services. The insurance industry and Health Insurance Association of America promise to fight it.

At the AMA meeting an issue emerged relative to the gasoline additive which is an octane enhancer—manganese. Initially many people could not understand why it was a big issue. Apparently there are possible health hazards, especially after auto accidents when gasoline with manganese may spill on roads and seep underground, possibly into water supplies. It was mentioned that this is the number one issue in the Maine gubernatorial race this year.

Mr. Norbeck informed the Council that a friend, Bill DeMarco, has authored a book for the McGraw-Hill Healthcare Education Division entitled: *Physician Driven Health Plans—Innovative Strategies for Restoring Physician-Community Integration.* The book is about how physicians can be restored to their appropriate leadership role. Mr. DeMarco is a very physician-friendly consultant who was involved in the early days of MDHP. Mr. Norbeck was asked to write an endorsement for it, no fee or remuneration involved, and asked the Council's approval to write this endorsement. It was VOTED to approve Mr. Norbeck's request.

Legislative Update

Dr. David Parke, chair of the Legislative Committee, informed the Council that it was a successful legislative session and directed their attention to the document distributed with the agenda from Sullivan & LeShane entitled "Final Legislative Wrap-Up." It was reported that the committee is now beginning to plan for the session ahead. He reported that Dr.Timmerman, Chair of COMPAC, will stress how important it is to get involved in the election process to ensure another successful legislative year.

There will be many bills coming before the legislative session next year, however; he reported, there are three important issues already on the horizon. The first issue involved the osteopathic physicians. Osteopathic physicians and medical physicians are licensed under two different chapters of the statutes. This Council consented to supporting legislation to incorporate D.O.s into the M.D.'s licensing statute and expand the Medical Examining Board to govern the practice of allopathic and osteopathic medicine. The 1995 proposal died in the House due to the any-willing- provider amendment that was filed on it. At the present time, discussion is underway with the D.O.s and the Department of Public Health to assess the possibility of revisiting the merging of licensure statutes. One main issue that is being discussed with the Department of Public Health is the protection of the confidentiality of any D.O.s who are working with the Physician Health Program until such time that, with the consent of the Council, a legislative remedy can be accomplished through a merger of licensure statutes. It was VOTED to authorize Dr. Parke to go forward with the proposal of joining the boards.

The second issued involves the crucial issue of patient confidentiality. CSMS has been working with a coalition of health-care providers, mostly mental health professionals, who are very concerned with the effect of managed care on patient confidentiality. Rather than proposing legislation, the coalition agreed that a reasonable approach would be to ask the state legislature's Law Revision Commission to do a comprehensive study of all the current state statutes that deal with patient confidentiality. This study should result in a comprehensive report on the status of our state confidentiality laws and a recommendation for legislative changes. It will also provide an opportunity for the coalition to recommend positive change and to defend against unwanted change. CSMS has been asked by the Connecticut Coalition for Patient Confidentiality to officially join the coalition. Although not an official member, CSMS has been a very active participant in the coalition meetings. The goal of the coalition is to advocate for comprehensive, user-friendly state legislative reform that will protect the confidentiality of medical and psychiatric reforms. No monetary contribution is required. It was VOTED to approve CSMS's membership in the coalition.

The third issue involves the expanding practice of physicians performing outpatient surgery in the office. While a surgical center and a hospital are both subject to licensure and certificate of need regulations, a physician's office practice that is performing outpatient surgery is not subject to either. This disparity has become an urgent issue for some hospitals as they have become aware of expanding outpatient surgery practices within their markets. The hospitals feel threatened and have put pressure on the Connecticut Hospital Association to take some action. It was noted that this issue has been raised several times within the Office of Health Care Access's Certificate of Need Task Force. Although the economics of the issue is a driving force, there are also potential issues of patient safety, physician credentialing, quality assurance, and self-policing. Dr. Parke sought the opinion of the Council as to how to address this issue. It was VOTED to endorse physicians' right to practice surgery in their offices and in surgicenters. It was further VOTED that CSMS legal counsel on this issue should be different from the hospital counsel. The chair of the Council asked that the president appoint a committee to meet with Dr. Parke to help him interact with the Department of Public Health on the issue of surgicenter regulations.

Report of AMA Delegation

Dr. Sadowski, chair of the AMA delegation, stated that all the reference committees are held simultaneously, and it is impossible for one person to cover all of the sessions. The delegates were assigned to various reference committees and reported on the activities of the reference committees. The actions of the AMA House of Delegates are reported in *AMA News*.

Report on COMPAC

Dr. Donald Timmerman, chair of the COMPAC Board, reported the COMPAC membership statistics for the Council, officers, and county associations. The goal is to get 14% in each county and he stated that if that were accomplished, it would break a record that was set 200 years ago. He stated now is the time to be setting our professional goals and ideals before the next group of legislators takes office. He discussed the possibility of having fund raisers for various candidates and described the different types that could be held, such as a member collecting funds from a small group of physicians, hosting a private luncheon for a legislator, etc. He announced that the next Council meeting will be a fund raiser for two legislators and asked the councilors to bring their check books to the next council meeting. A document entitled "The 1998 CSMS/COMPAC Legislative Award Nominees" was distributed listing the nominees. There are 32 nominees, and it is planned to make these awards at a reception in September, with the two top awards presented at the semi-annual meeting of the House of Delegates in November. It was VOTED to approve the list of nominees.

Committee on Public Affairs

It was VOTED to approve the recommendation of the Committee on Public Affairs that the Council approve and support the Society's sponsorship of an Alzheimer's conference for physicians and caretakers to be held in conjunction with the State of Connecticut Department of Aging, Alzheimer Northern Connecticut Chapter and Bayer Corporation on 28 October 1998, at the Radisson Hotel in Cromwell. There were no fiscal requirements.

Committee Appointments

Committee on Medical Aspects of Sports: Voted to appoint Steven B. Carlow, M.D., Groton, to the committee.

Committee on Public Health: Voted to appoint Paul S. Goldstein, M.D., New Haven, to the committee

Committee on Public Affairs: Fairfield County submitted the name of James W. Innes, M.D., Old Greenwich, as their county nominee on the subject committee.

CSMS-IPA Nomination from New London County

Dr. Deren read a letter from the president of the New London County Medical Association stating that the Board of Trustees of the New London County Medical Association voted not to renominate David D. Thompson, Jr., M.D., as the county-elected director of the CSMS-IPA, and nominated Joseph Zeppieri, M.D., Groton, as the county-elected director of the CSMS-IPA. Dr. Deren also read from a letter he received from Dr. Ducey, president of the New London County Medical Association, outlining Dr. Thompson's activities regarding his nomination to the CSMS-IPA board and his efforts to overthrow the action of the New London County Medical Association. Dr. Thompson informed the county medical association that Dr. Zeppieri was not eligible to serve on the board since he was not a primary care physician. It was VOTED that the CSMS Council supports the action of the Board of Trustees of the New London County Medical Association, and that a letter be sent by the Council to the president of the New London County Medical Association and M.D. Health Plan informing them of the Council's action. In response to questions, CSMS legal counsel informed the Council that as the sole shareholder, it had final approval of all the nominees submitted and had the authority to change the nominating process and bylaws. It was suggested that the president and chairman of the council consult with legal counsel to ensure that all proper actions are taken in setting the agenda for the next meeting with regard to the vote on the CSMS-IPA.

Dates of Future Meetings

The dates of the following meetings were approved:

Council Meetings—Wednesday, 26 August 1998
Thursday, 15 October 1998

Semi-annual Meeting—House of Delegates,
Thursday, 19 November 1998

Annual Meeting—House of Delegates,
Wednesday, 12 May 1999

Semi-annual Meeting—House of Delegates,
Wednesday, 17 November 1999

BOOK REVIEW

Tales My Stethoscope Told Me
by Martin Duke, 139 pp. $10.00, ISBN 1-56474-258-X, Santa Barbara, California: Fithian Press, 1998

Recently an ophthalmologist friend, after telling me about his two sons who were in their residency or fellowship programs, exclaimed "Medicine, what a life! There's nothing better. Even if it paid only minimum wage, I'd do it again." We were speaking about the memories, the stories that made up the life of a doctor—he had cared for four generations of our family, and together we had some stories to tell. Sooner or later, every physician, given half a chance will begin a story, "I had a patient once...."

Martin Duke has written his second book, this time filled with doctor stories, *Tales My Stethoscope Told Me.* From the warmth and affection and high spirits that fill these tales, it is clear that he, like most of us, would do it all over again! His earlier book, *The Development of Medical Techniques and Treatments: From Leeches to Heart Surgery,* was an expression of his long fascination with medical history, but medical history, a hiding place for many of us when we needed a retreat, could never take the place of the human connections he made with his stethoscope. In his preface, Dr. Duke quotes the Nobel laureate, Dickenson W. Richards:

> In order for the stethoscope to function, two things have to happen. There has to be, by God, a sick man at one end of it and a doctor at the other! The doctor has to be within thirty inches of his patient ... It might not be too presumptuous to suppose that in being this close to his patient, the doctor might hear, see, feel, or otherwise apprehend something more beyond the momentary lup-dup (sound) in the earpiece,

I liked this quotation, looked it up, and found that it was from Richards' Presidential Address to the Association of American Physicians in 1962, "Medical Priesthoods Past and Present." Where Dr. Duke inserted the four dots after "patient" I hope he won't mind if I fill in Richards' words that followed and had been, in the interest of space, left out:

> It won't work by long distance telephone, or by word of mouth through half a dozen intermediaries, or by radio, or by television, or in a dry clinic, or even in a committee. And don't think that right now I am just aiming a peashooter solely at the academic doctor. This is an old-fashioned Miles Standish blunderbuss aimed at everybody.

His stories begin in 1954, his internship year, and end in June 1993 as he closes his office in Manchester after almost 30 years of practice in this central Connecticut town, much of that time as the only cardiologist. Here, the final lines from his Epilogue:

> I glance around the almost vacant office and in my mind's eye see Rose sitting at the reception desk talking to a patient—is that Joan Mozzer with a thin plastic tube running from her nose to the portable oxygen unit at her side, Sara Edmunds describing her chest pains in her pronounced English accent, or ninety-two-year-old Angela Zepponi with a bulge beneath her collar bone where the battery for her pacemaker is implanted? The images blur—perhaps there is something in my eyes.
>
> I retrieve my stethoscope and leave, taking my tales with me.

These are not just "I had a case" stories, clinical accounts of strange medical events and amazing diagnoses, but very human tales about a doctor, his patients, his town, and his family and the career-long struggle that we have all faced in balancing the demands of our beloved profession, the needs of our patients, and our love for our families.

In his presidential address that Dr. Duke quoted, Dickenson Richards reminded his audience of academic internists of Hippocrates' admonition: "It is necessary for the physician to provide not only the medical treatment, but to provide for the sick man himself, and for those beside him, and to provide for his outside affairs." No easy task.

Dr. Duke, recounting these tales of doctoring and life, has described across almost a half century the kind of medical practice that may be fading fast, despite all our attempts to recover it. Imprisoned by technology and the corporate demand for profit, a doctor now has little time for house calls and sharing a glass of homemade wine with an elderly Italian widow after attending to her congestive heart failure. In his foreword to *Tales My Stethoscope Told Me*, Dr. Howard Spiro remarks that "First, American doctors lost their empathy and now they are losing their freedom. Even more disturbing is that they are in danger of losing the attention, the love and the respect of their patients." Managed care, from what I hear, has little room for doctor stories, at least not the kind of stories most of us would be cheered by hearing.

As we finish reading these tales of patients and places and family, we may feel assured that the author's two daughters, both physicians, will carry on their father's traditions, holding on to "the attention, the love, and respect of their patients." And that perhaps, after the corporate management types find other venues to pursue their skills, physicians may once again discover the deep satisfaction of our profession.

Robert U. Massey, M.D.
Avon

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CONSUMER AFFAIRS DIVISION
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Phone: (860) 297-3900 or 1-800-203-3447 Fax: (860) 297-3872

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In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

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Address: ______________________________________

Phone where the Department can contact you: (_____) ____________________

This concern or complaint concerns the following Insurance Company or Managed Care Plan: ______________________

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Name of Policyholder: __________________________

Name of Enrollee: ______________________________

Name of Patient: ______________________________

Patient is ___ self ___ dependent ___other (explain)______________________

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Connecticut Medicine

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VOLUME 62 SEPTEMBER 1998 NUMBER 9

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scientific:

Brian W. Cooper and Elain Morganelli 515 **Group B Streptococ in Adults at Hartfor**

Douglas R. Linfert, William N. Rezuke, and Gregory J. Tsongalis 519 **Rapid Multiplex An and Prothrombin G with Hereditary Th**

David P. Neumann, Robert J. Scholl, Helen M. Kellet, and Richard H. Simon 527 **Magnetic Resonanc**

Gary King, Richard Strouse, Deborah Anne Hovey, and Lori Zehe 531 **Cigarette Smoking in Connecticut: Home and Workplace Exposure**

Epitomes of Progress
Daniel A. Nachtsheim 541 **Important Advances in Clinical Medicine—Urology**

Morbidity and Mortality Weekly Report
547 **Civilian Outbreak of Adenovirus Acute Respiratory Disease—South Dakota, 1997**

The Medical Letter
551 **Vitamin Supplements**

departments:

Fifty Years Ago
553 **Actuarial Society Analyses Surgical Benefit Claims**
553 **First International Poliomyelitis Conference**

The President's Page
Craig W. Czarsty 555 **COMPAC Revisited and a New Editor for *Connecticut Medicine***

Reflections on Medicine
Robert U. Massey 557 **A Question of Virtue**

Medical News Capsules
Timothy B. Norbeck 559 **This Month's Reading in Review**

CPRO Corner
CSMS 561 **CPRO Focus Is Now on Quality Improvement Through Collaboration**

Letters to the Editor
Morris A. Wessel 563 **Thanks**
Allen R. Koenig 563 **Anonymous Poem "My Daddy, M.D."**

From the Executive Director's Office
565 **Call**

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general:

567 **In Memoriam**
569 **CSMS Physician Placement Service**

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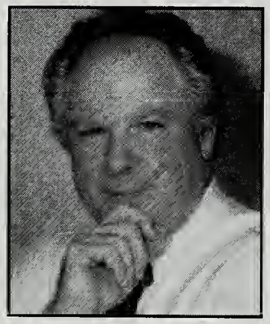

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Group B Streptococcal Bacteremia in Adults at Hartford Hospital 1991–1996

BRIAN W. COOPER, M.D., AND ELAINE MORGANELLI, B.A.

ABSTRACT—Invasive disease due to Group B streptococci has been increasingly recognized as a problem in chronically ill adults. We studied all adults presenting with bacteremia due to Group B streptococci at Hartford Hospital over a period of more than five years. Fifty-nine episodes of septicemia occurred with a mortality rate of 15.3%. Markers for mortality included cirrhosis, azotemia, transaminase elevation, respiratory distress on admission, and ionized hypocalcemia Although commonly thought of as a maternal and pediatric pathogen, nonpregnant, chronically ill adults make up the vast majority of patients with Group B streptococcal sepsis.

Introduction

GROUP B streptococcal infection among newborns has long been recognized as an important public health issue. Recently, there has been increasing awareness of the importance of invasive Group B streptococcal infections in adults. It has been estimated that more than 7,000 cases of invasive Group B streptococcal disease occur annually in the United States. Both nosocomial and community acquired infections have been described.[1] Previous studies have identified groups of adults who are at risk for invasive Group B streptococcal disease. Patients at increased risk include diabetics, cancer patients, and those with chronic neurologic disease.[1–3] Reports of invasive Group B streptococcal infections have included wound infections, cellulitis, osteomyelitis, septic arthritis, urinary tract infections, meningitis, and pneumonia. Bacteremia, both with and without an underlying focus is one of the most common invasive Group B streptococcal diseases.[2,3]

Recent research on vaccine development for Group B streptococcal infection has important implications for both newborns and adults who are at risk for invasive Group B streptococcal disease.

We conducted a descriptive study of adults with Group B streptococcal bacteremia over a 64-month period at Hartford Hospital in order to describe underlying illness and outcomes associated with bloodstream infections due to this pathogen.

Materials and Methods

Hartford Hospital is an 850-bed teaching hospital. The hospital serves a large central Connecticut population as both community hospital and tertiary care center. The medical records of all patients diagnosed with Group B streptococcal bacteremia in the period from January 1991 to April 1996 were reviewed for this study. All records were identified retrospectively by analysis of a computerized data base of microbiologic data at Hartford Hospital. Records were reviewed, and a line listing of demographic risk factor and outcome data recorded. Data included preexisting risk factors, clinical characteristics on admission, laboratory values within the first 48 hours of diagnosis, and clinical outcomes. Nosocomial bacteremia was defined as a positive blood culture which was obtained greater than 48 hours after admission. Data were analyzed by Epi-Info 6.0. Categorical variables were compared with χ^2 or Fisher's exact test when appropriate. Continuous variables were compared with t-test or, when appropriate, with Kruskal Wallis test for two groups.

BRIAN W. COOPER, M.D., Division of Infectious Diseases, Hartford Hospital, associate professor of clinical medicine, University of Connecticut School of Medicine, Farmington; ELAINE MORGANELLI, B.A, Division of Infectious Diseases, Hartford Hospital, Hartford.

Results

A total of 59 episodes of Group B streptococcal sepsis occurred in 57 patients. Cases occurred throughout the year and there was no clustering by seasons. Crude numbers of infections were similar from year to year and no outbreaks were identified in this period of time. The median age was 57 years with a range of 23–92. This was similar to the number to the median age of our general hospital population (adults only). Thirty-nine patients were white, 13 black, six Hispanic, and one other. Blacks were over represented in the group of infected patients compared to the general hospital population (22% *vs* 8.5%, P <.002). Two of the 59 patients had multiple organisms isolated in blood cultures, while the remainder had only Group B streptococci. There were 34 (57.6%) females and 25 (42.4%) males. Four of the females were previously healthy pregnant women but the vast majority of the other patients had one or more underlying medical problems. Only two of the 55 nonpregnant patients had no identified underlying chronic medical problems. Underlying risk factors are listed in Table 1. The most frequent predisposing disorders include cardiovascular disease in 21 (35.6%), diabetes in 21 (35.6%), cirrhosis in 11 (18.6%), and malignancy in 11 (18.6%).

Laboratory abnormalities present on diagnosis or within 48 hours of diagnosis included transaminase abnormalities greater than twice normal in 13 (22.4%) and thrombocytopenia (thrombocytes less than 150,000/mm^3) in 32 patients (54.2%). Among 39 patients who had coagulation studies done, 20 (51%) were abnormal. Serum ionized calcium was measured in 44 patients and hypocalcemia was noted in 22 (50%).

Other clinical characteristics present upon diagnosis included hypotension in six (10.2%), respiratory distress in seven (11.9%), and renal impairment (creatinine > 2.0 mg/dL or > 1.0 above baseline) in 13 patients (22%). The source of infection was identified in 12 (20.3%), including nine skin or soft tissue infections and three with urosepsis. The source of bacteremia was unknown in 47 patients (79.6%).

Table 1.—Underlying Medical Conditions

Conditions	N (%)
Cardiovascular disease	21 (35.6)
Diabetes mellitus	21 (35.6)
Alcohol abuse	17 (28.8)
Cirrhosis	11 (18.6)
Malignancy	11 (18.6)
Peripheral vascular disease	8 (13.6)
Neurologic disorders	8 (13.6)
Hemodialysis	6 (10.2)
Pregnancy	4 (6.8)
HIV infection	3 (5.1)
Chronic pulmonary disease	2 (3.4)

The overall mortality was nine (15.3%). None of the four pregnant adults died. All patients who died had at least one underlying chronic medical problem. When stratified by mortality, a number of risk factors were associated with death by univariant analysis (Table 2).

Among underlying medical problems, only patients with cirrhosis were at significant risk of death, four of 11 (36%) cirrhotic patients died. Among laboratory markers of increased mortality, renal impairment, abnormal transaminases, and abnormal coagulation studies were associated with adverse outcome. Patients with ionized hypocalcemia were at significantly higher risk of death than with normocalcemic patients. Eight of 22 (36.3%) of hypocalcemic patients died *vs* one of 20 (5%) of normocalcemic patients. Mortality was similar among hypotensive and normotensive patients but was excessive in patients who presented with respiratory distress.

Ten patients had nosocomial bacteremia (16.9%). Patients with nosocomial bacteremia had mortality rates similar to those with community acquired disease; 20% *vs* 14.2% respectively ($P = 0.6$).

When stratified for mortality no difference was found in the mean age or mean white blood cell count among those who died. There was no difference in mortality among those over 65 *vs* under 65 ($P = 0.47$) but this may be due to the relatively small numbers of deaths.

One elderly patient in our group had relapsing infection and presented with Group B streptococcal sepsis in September 1991, July 1992, and June 1993. In no case was an underlying source found. Relapsing episodes of Group B streptococcal sepsis have previously been described.[5,6]

Conclusion

Group B streptococci have long been recognized as pathogens in pregnant adults. In our population, nonpregnant adults accounted for 93.2% of all cases of Group B streptococcal bacteremia in adults. Although our study was not population based, we found an incidence of 0.31

Table 2.—Factors Associated with Mortality

Riskes	% Mortality	Significance (*P*)
Cirrhosis	36.3	0.05
Azotemia	38.4	0.01
Transaminase elevation	38.4	0.02
Respiratory distress	57.1	0.007
Hypocalcemia	36.3	0.05

per 1,000 adult hospital admissions which is similar to rates reported by others.[2] Group B streptococcal bacteremia appears to be a disease primarily of patients with serious underlying medical conditions. In this study, only two nonpregnant adults with Group B streptococcal bacteremia had no underlying serious medical conditions and most patients had more than one. As in other studies cardiovascular disease, diabetes, cirrhosis, and malignancy were the most common underlying disorders. Interestingly, despite an active HIV service at Hartford Hospital, there were few HIV+ patients with Group B streptococcal bacteremia in this five-year period. This is in agreement with most other studies completed during the AIDS era.

Our patient population had a relatively low number of nosocomial infections (16.9%) but six of the community acquired bacteremias occurred in nursing home residents. Other studies indicate a similar proportion of nosocomial infections ranging from 17% to 25%.[1–4]

Mortality in our study was associated with cirrhosis which is known to result in profound defects in reticuloendothelial defenses. Nearly half of the patients who died had cirrhosis.

Hypocalcemia has been described previously as a sequela of sepsis and is not specific to streptococcal sepsis, but the high rate of hypocalcemia (51%) in this study was surprising.[7,8] Hypocalcemia occurring in the first 48 hours of sepsis was also a significant marker for mortality in our group. Eight of the nine patients who died had hypocalcemia at the onset of sepsis.

In summary, we have found that nonpregnant adults make up the vast majority of patients at our institution with Group B streptococcal sepsis. Most cases occurred in patients with serious underlying illness. Hypocalcemia within the first 48 hours of sepsis was strongly associated with mortality in this group. Significant advances have been made recently in the development of a Group B streptococcal vaccine.[9,10] In addition to pregnant women, testing of candidate Group B streptococcal vaccines will need to include adults with risk factors associated with Group B streptococcal disease in order reliably to estimate efficacy.

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Rapid Multiplex Analysis for the Factor V Leiden and Prothrombin G20210A Mutations Associated with Hereditary Thrombophilia

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AND GREGORY J. TSONGALIS, PH.D.

ABSTRACT—Thromboembolic episodes are common events and affect approximately one in 1,000 persons annually. Pulmonary embolism alone accounts for 50,000 to 100,000 deaths per year in the United States with >50% of those being elderly persons. Resistance to activated protein C is the most common inherited disorder associated with hereditary thrombophilia. A missense mutation has been identified in the gene coding for coagulation factor V (codon 506) which renders this procoagulant factor resistant to inactivation by activated protein C resulting in an increased risk for venous thrombosis. Recently, a second polymorphism was identified in the prothrombin gene (factor II) which is also associated with increased risk for venous thrombosis. Because of the high prevalence of these two mutations in the general population as well as in specific patient populations, the ability readily to detect these two mutations must be feasible. In this study, we evaluated 303 patients for the prothrombin mutation (G20210A) which were previously tested for the factor V mutation using established polymerase chain reaction-mediated restriction fragment length polymorphism assays. In these patients, 30 (9.9%) were found to be heterozygous for the factor V Leiden mutation with no homozygous mutants identified. Twenty individuals (6.6%) were heterozygous for the prothrombin G20210A mutation, and we identified two individuals (0.66%) who were homozygous for the 20210A allele. Of the total 303 individuals screened, two were double heterozygotes for both the factor V Leiden and the prothrombin gene mutations. We also describe a multiplex polymerase chain reaction-mediated restriction fragment length polymorphism assay for detecting both mutations in a single-tube double-enzyme digestion reaction making identification of these two mutations easily achievable.

Abbreviations Used in Text
APC = activated protein C
PCR = polymerase chain reaction
RFLP = restriction fragment length polymorphism
UT = 3'-untranslated
EDTA = ethylenediamino tetracetic acid
DVT = deep vein thrombosis
PE = pulmonary embolism

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Introduction

VENOUS thrombosis has a worldwide annual incidence of approximately one in 1,000 individuals and represents a major cause of morbidity and mortality that commonly results from associated pulmonary embolism.[1] While coagulation remains a highly complex biochemical process, epigenetic and genetic risk factors have been identified for increasing individual risk for thrombosis. Epigenetic risk factors include the precipitating factors of major surgery, trauma, oral contraceptive intake, pregnancy, prolonged immobility, and obesity.[1] Deficiencies in antithrombin, protein C, or protein S were once the only recognized inherited abnormality commonly associated with increased risk for venous thrombosis. However, together these genetic risk factors, which are physiologic inhibitors of blood coagulation, account for only 5% to 15% of thrombophilia cases allowing the etiology of 85% to 95% of familial cases to be indeterminate.[1–8]

While many mutations in genes involved in the coagulation cascade have been identified, the most common genetic defect responsible for hereditary thrombophilia is the mutant factor V gene (factor V Leiden) responsible for activated protein C (APC) resistance.[9-12] In 1993, Dahlback et al described this defect in the protein C related coagulation pathway as an inherited resistance to the anticoagulant action of APC.[10] Protein C is a circulating anticoagulant, an important regulator of hemostasis, and circulates in plasma as an inactive zymogen which is converted to APC by thrombin (Fig. 1).[1] APC mediates its anticoagulant effect by inactivating factors Va and VIIIa, which are cofactors involved in the intrinsic and extrinsic coagulation pathways (Fig. 1). Inherited resistance to APC occurs in most cases because of a single-point mutation in the gene for factor V which results in a simple amino acid substitution in the protein, thus resisting inactivation by APC and resulting in an increased risk for thrombosis. Despite the increased prevalence of the factor V Leiden mutation in individuals with prior history of thrombosis (20% to 50%), the underlying molecular mechanism of many thromboembolic events remains unknown.[9,13-14]

Recently, another genetic variation has been identified in the 3'-untranslated (UT) region of the prothrombin gene which is also associated with increased risk of venous thrombosis.[15] Prothrombin is the precursor to thrombin in the latter portion of the coagulation pathway which leads to the formation of fibrin (Fig. 1). The prothrombin gene consists of 14 exons spanning approximately 21 kb at position p11-q12 of chromosome 11.[16,17] A single G to A point mutation at nucleotide position 20210 was found to be associated with an increased risk for venous thrombosis and higher prothrombin levels.[15]

In this study, we examined 303 patients who suffered or were suspected of having had thromboembolic episodes for the described molecular defects in these two genes. Using two polymerase chain reaction-mediated restriction fragment length polymorphism (RFLP) assays for the detection of the factor V gene mutation and the prothrombin gene mutation we demonstrate the feasibility of a multiplex polymerase chain reaction (PCR) and double enzymatic digestion to detect both of these genetic defects in a single assay.

Materials and Methods

Clinical Specimens.—Peripheral blood samples from patients with a history of hypercoagulability were collected in lavender ethylenediamino tetracetic acid (EDTA) vacutainer tubes from 303 individuals from January to December 1997. These specimens were initially obtained for analysis of the factor V Leiden mutation. We subse-

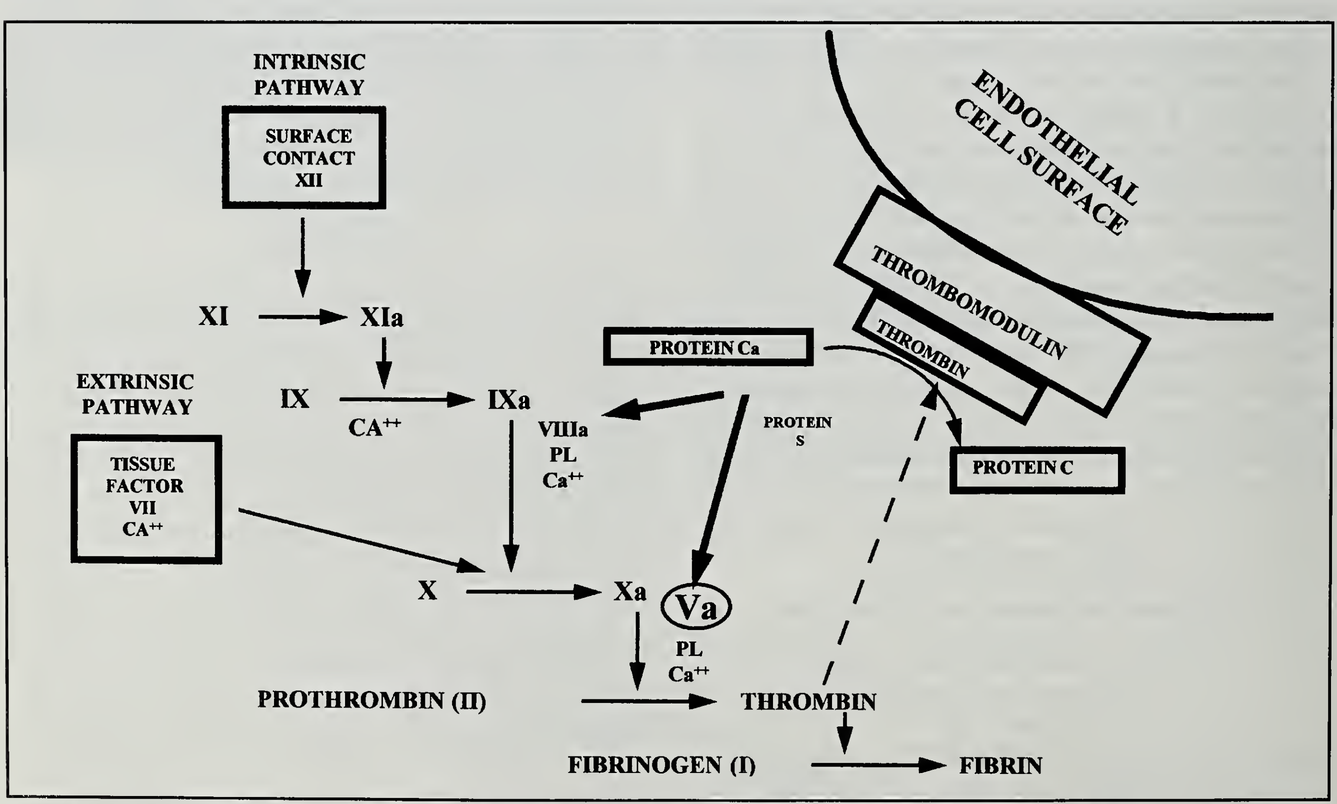


Figure 1.—Schematic representation of both the intrinsic and extrinsic coagulation pathways. Abnormalities in Factor V and/or prothrombin (Factor II) result in disruption of this highly regulated coagulation cascade.

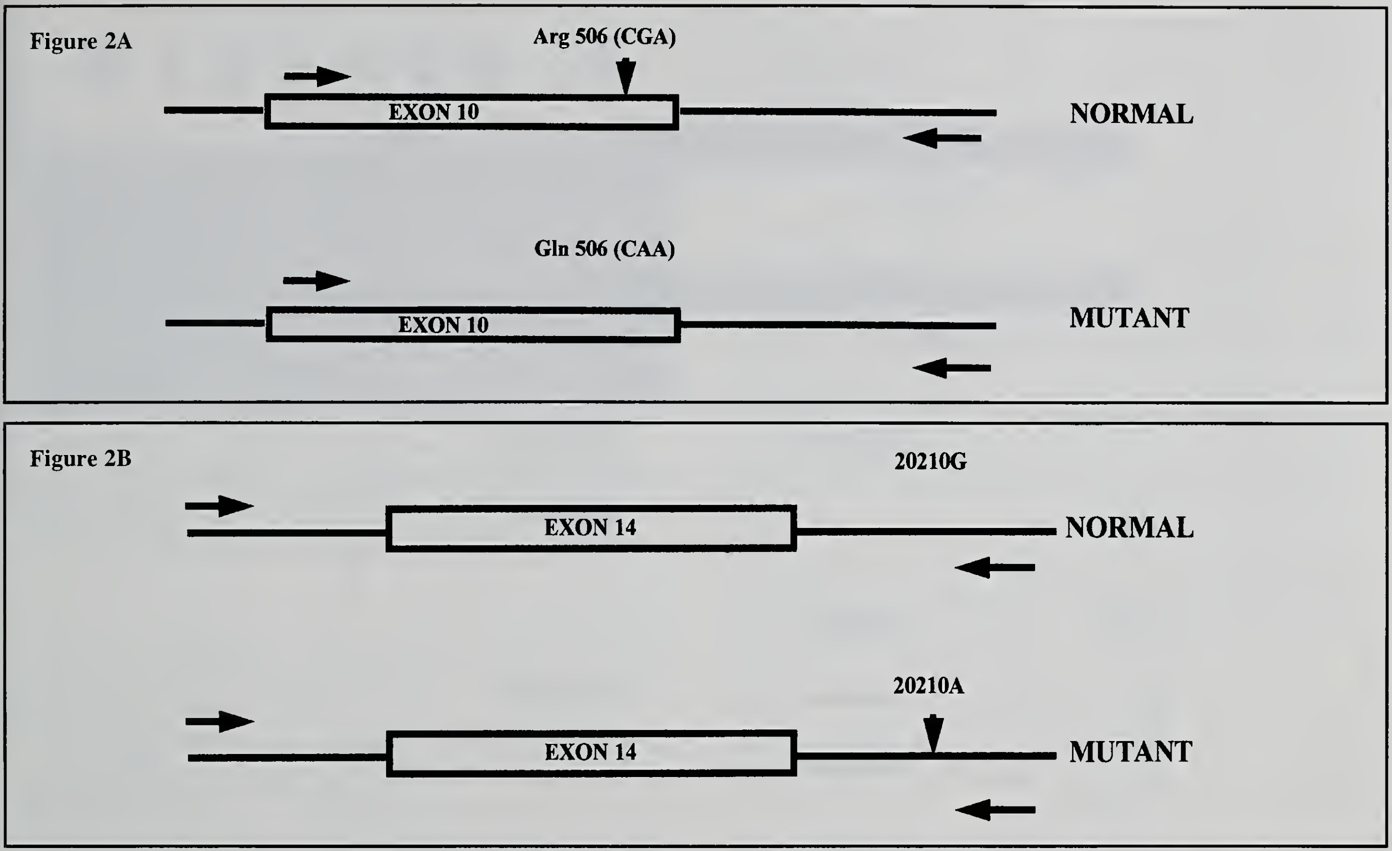


Figure 2.—Schematic representation of the factor V (A) and prothrombin (B) normal and mutant alleles. Location of primers, arrows; site of mutation, arrowhead.

quently screened each DNA sample for the prothrombin G20210A mutation in a blinded study in which all patient identifiers were stripped.

DNA Isolation.—DNA was extracted from peripheral blood leukocytes using the Puregene extraction kit (GENTRA, Systems, Inc., Minneapolis, Minn.). Briefly, red blood cells were first lysed and removed by centrifugation. The remaining cell pellet was then resuspended in cell lysis solution. Subsequent to protein precipitation, the supernatant was removed to a clean microcentrifuge tube containing 300 µL 100% isopropanol to precipitate DNA. DNA hydration solution was then added and the sample allowed to rehydrate overnight at room temperature or at 65° C for one hour.

Mutation Analysis.—Genomic DNA (0.5-1.0 µg), isolated as described above, was incubated in a total reaction volume of 50 µL containing 40 ng of both the forward and reverse gene specific primers, 2.0 units AmpliTaq Gold (Perkin-Elmer, Norwalk, Conn.), 200 µM each deoxynucleotide triphosphate, 1.5 mM $MgCl_2$, 10 mM Tris-HCl (pH 8.3), 50 mM KCl, and 0.001% gelatin. The primers used for the factor V Leiden mutation were as follows: 1691G forward primer, 5'-ACC CAC AGA AAA TGA TGC CCA-3' and 1691G reverse primer, 5'-TGC CCC ATT ATT TAG CCA GGA-3';[18] whereas, the primers used for the prothrombin 20210 mutation were the following: prothrombin forward primer, 5'-TCT AGA AAC AGT TGC CTG GC-3' and prothrombin reverse primer, 5'-ATA GCA CTG GGA GCA TTG AAG T-3'.[15] DNA was initially denatured at 94° C for 11 minutes prior to amplification in the Perkin Elmer 2400 thermocycler. PCR amplification was accomplished using 35 cycles consisting of 30 seconds denaturation at 94° C, 30 seconds annealing at 55° C, and 30 seconds extension at 72° C. The final cycle included a three-minute extension step at 72° C. The factor V Leiden mutation associated with APC resistance destroys an Mnl I restriction enzyme recognition sequence and is thus detected by digestion of PCR amplified products with this enzyme (Fig. 2A).[18] The restriction digestion was performed in a total volume of 50 µL and consisted of 30 µL PCR product, 14 µL distilled water, 10 units Mnl I enzyme (New England Biolabs, Beverly, Mass.), and 5 µL 10X buffer. Samples were then incubated for a minimum of three hours at 37° C. Restriction fragment size analysis was performed by visualization of digested PCR products after separation by gel electrophoresis in a 10% polyacrylamide gel and staining with ethidium bromide. Similarly, when amplified using a mutagenic primer, a Hind III restriction site is introduced into the prothrombin 20210 mutant allele (Fig. 2B).[15]

Figure A

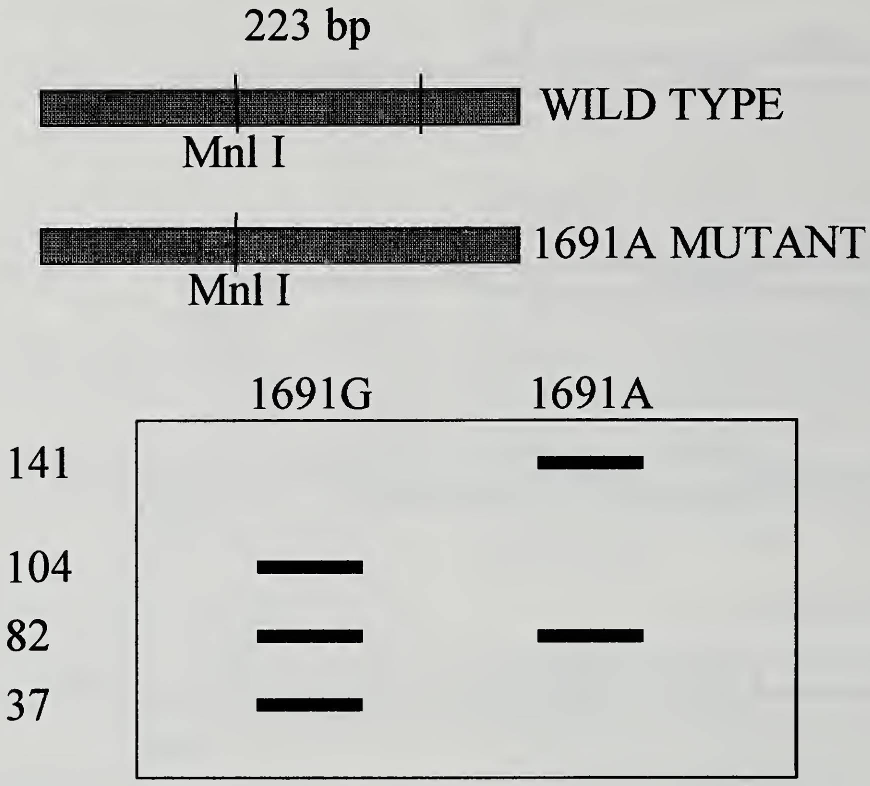
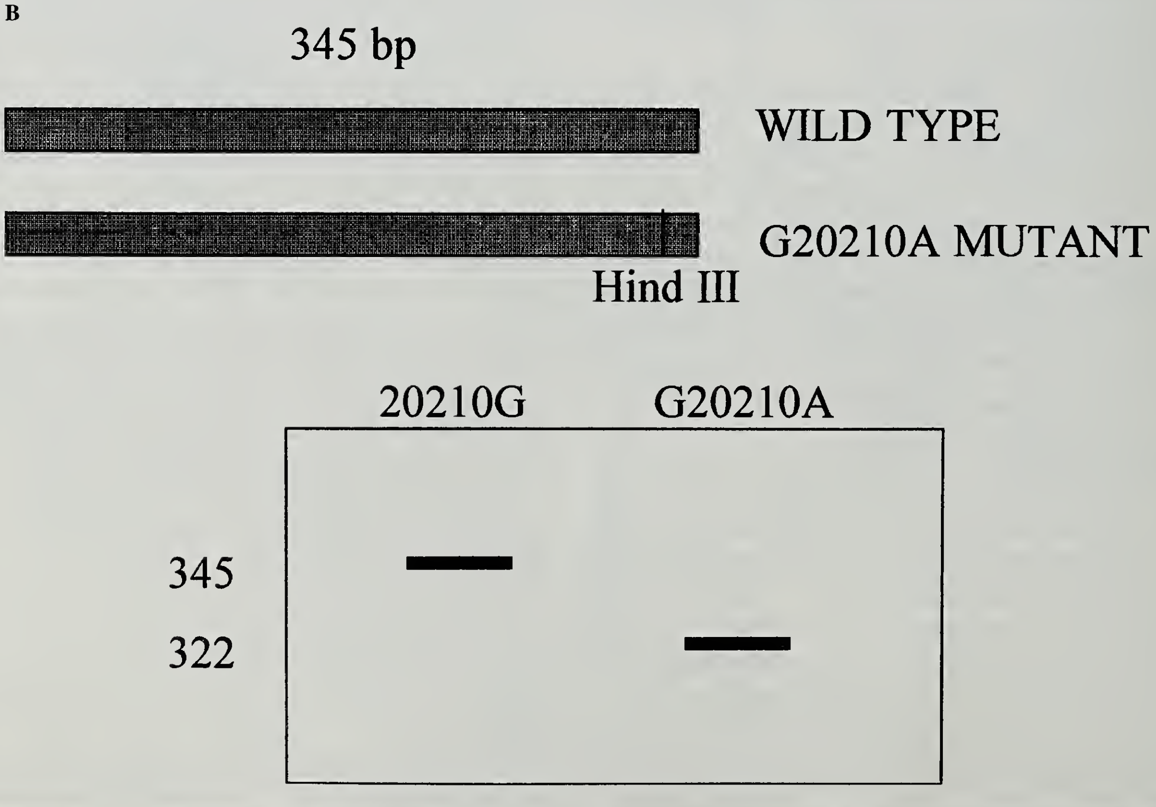


Figure 3.—PCR-mediated analysis for the factor V Leiden (A) or the prothrombin G20210A (B) mutations. The rectangular box represents the PCR product from each gene and restriction endonuclease sites are given by solid lines. The wild type and homozygous mutant banding patterns are depicted in the schematic gels.

Figure B



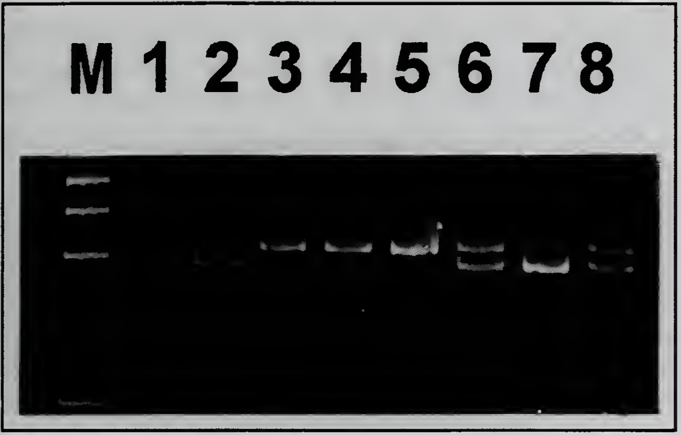


Figure 4.—Polyacrylamide gel electrophoresis of Hind III digested PCR products for the prothrombin G20210A mutation. Lane M, molecular size markers; Lane 1, blank control; Lane 2, homozygous mutant (+/+); Lane 3-5, normal (–/–); Lane 6, Heterozygous mutant (–/+); Lane 7, (+/+); Lane 8, (–/+).

Detection of this mutation is as described above for the factor V Leiden mutation with the one exception being the restriction endonuclease used.

A multiplex PCR reaction can be performed using both the prothrombin primers and the factor V Leiden primers in a single reaction. The amplification reaction conditions used were the same as those described above. Following amplification, a restriction digestion was performed in a total volume of 50 μL and consisted of 30 μL PCR product, 13 μL distilled water, 10 units each of Hind III and Mnl I enzymes, and five μL 10X buffer. Samples were then incubated for a minimum of three hours at 37° C. Restriction fragment size analysis was performed by visualization of digested PCR products after separation by gel electrophoresis in a 10% polyacrylamide gel and staining with ethidium bromide.

Results

DNA was isolated from 303 whole blood samples received from individuals who were clinically at risk for or had had a prior thromboembolic event. Factor V Leiden mutation analysis was performed using a PCR-mediated RFLP analysis (Fig. 3A).[18] Of the 303 individuals tested, 30 were found to be heterozygous for the factor V Leiden mutation. No homozygous mutants were detected and 273 individuals were shown to have the normal or wild type allele.

Subsequently, we screened these same 303 individuals for the 20210A mutation in the 3'-UT region of the prothrombin gene using a second PCR directed site-mediated mutagenesis assay (Fig. 3B).[15] Using a mutagenic primer, a 345 bp fragment which includes exon 14 and the 3'-UT region of the prothrombin gene was amplified by PCR which introduces a Hind III site, (-A/AGCTT), into the mutant allele. Upon digestion, the mutant G20210A allele yielded two fragments, 322 bp and 23 bp respectively, whereas the wild type 20210G allele was a single 345 bp fragment (Fig. 3B, Fig. 4). We identified 20 individuals (6.6%) who were heterozygous for this mutation. In addition, we also identified two individuals (0.66%) who were homozygous for the 20210A allele. Of the total

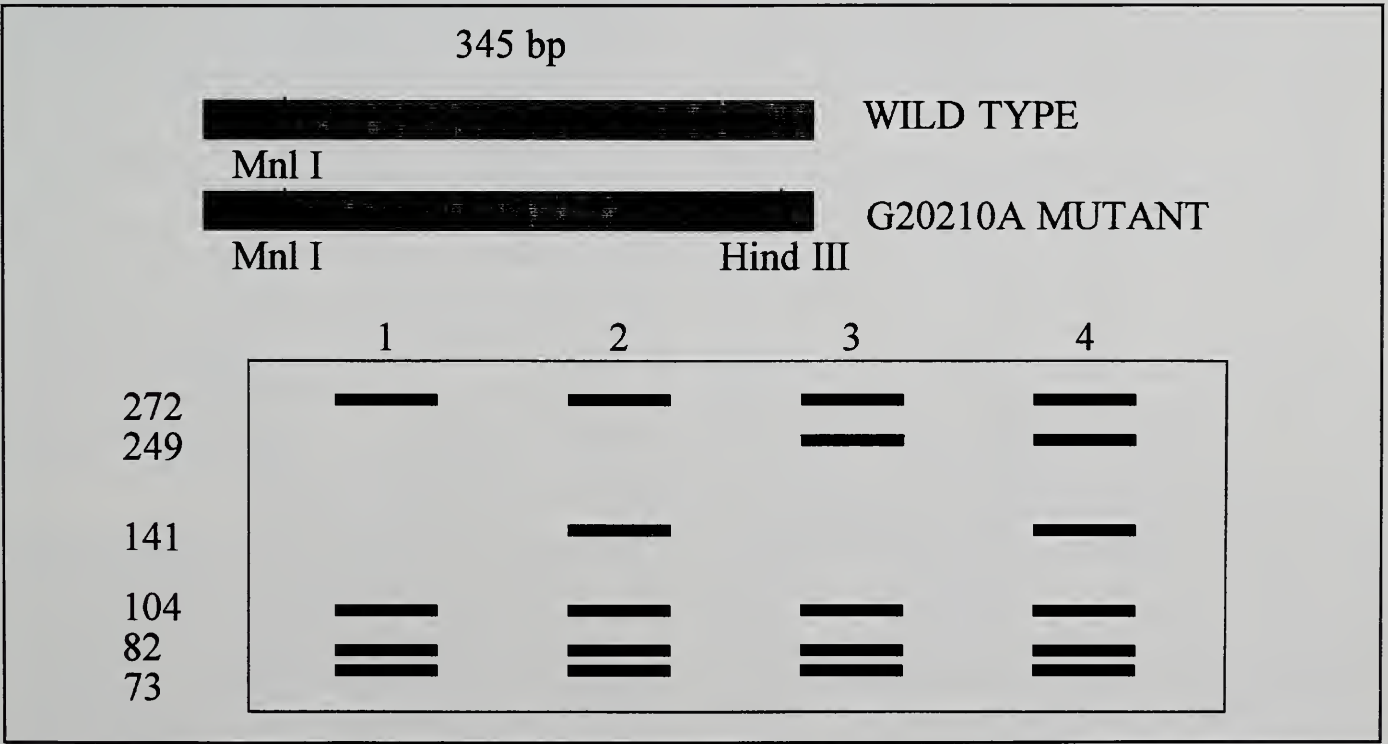


Figure 5.—Multiplex PCR and double digest detection of the factor V Leiden and prothrombin G20210A mutations. Banding patterns for the prothrombin and Factor V mutations are as follows: Lane 1, –/–, –/–; Lane 2, –/–, –/+; Lane 3, –/+, –/–; Lane 4, –/+, –/+.

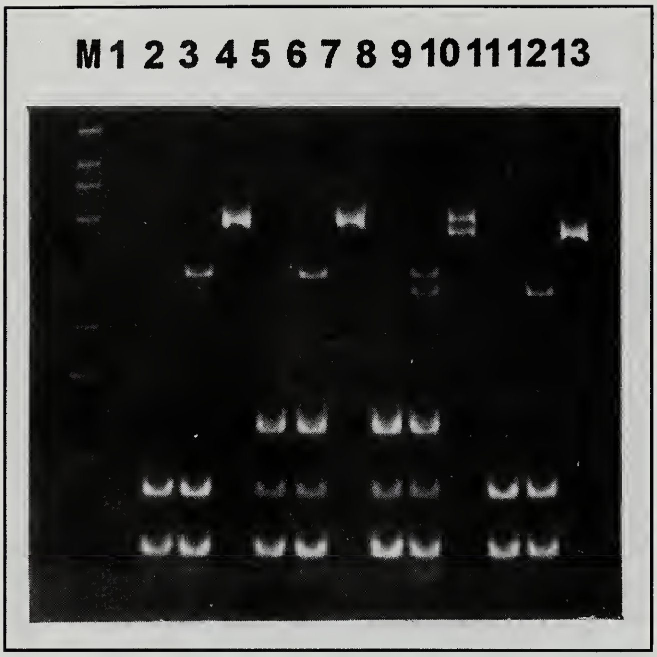


Figure 6.—Polyacrylamide gel electrophoresis of multiplex PCR and double enzyme digested PCR products. Lane M, molecular size markers; Lane 1, blank control; Lane 2, normal factor V (–/–); Lane 3, multiplex normal prothrombin/ normal factor V (–/–, –/–); Lane 4, normal prothrombin (–/–); Lane 5, Heterozygous factor V (+/–); Lane 6, multiplex normal prothrombin and heterozygous factor V (–/–,–/+); Lane 7, normal prothrombin (–/–); Lane 8, heterozygous factor V (–/+); Lane 9, multiplex heterozygous prothrombin and heterozygous factor V (–/+, –/+); Lane 10, heterozygous prothrombin (–/+); Lane 11, normal factor V (–/–); Lane 12, multiplex homozygous mutant prothrombin and normal factor V (+/+, –/–); Lane 13, homozygous mutant prothrombin (+/+).

303 individuals screened, two were double heterozygotes for both the factor V Leiden and the prothrombin gene mutations.

Because of the complexity of the coagulation pathway and the inclination of clinicians to pursue multiple laboratory tests in such patients, we examined the possibility of performing a multiplex PCR/double digest assay to detect both mutations in a single reaction. In our multiplex PCR reaction containing both the factor V and the prothrombin primers, simultaneous digestion with the Hind III and Mnl I restriction endonucleases yielded a prothrombin fragmentation pattern different from the single PCR/digest reactions. The presence of a Mnl I restriction site between nucleotide positions 19561 and 19562 in the prothrombin gene resulted in cleavage of a 73 bp fragment upstream of the mutation site (Fig. 5). The homozygous wild type pattern for prothrombin in our multiplex PCR-mediated RFLP assay yielded two bands at 272 bp and 73 bp respectively (Fig. 5, Fig. 6). The heterozygous banding pattern showed four restriction fragments at 272 bp, 249 bp, 73 bp, and 23 bp while the homozygous mutant banding pattern rendered three bands at 249 bp, 73 bp, and 23 bp (Fig. 5, Fig. 6). Because no Hind III restriction site exists in the factor V amplicon, the same banding patterns were observed in our multiplex PCR-mediated RFLP assay as in the single factor V Leiden RFLP assay (Fig. 5, Fig. 6).

Discussion

While numerous genes are involved in the coagulation cascade, most mutations identified in these genes to date are rare. The identification of the factor V Leiden mutation, the most common hereditary risk factor for thrombosis, is prevalent in both patients with a history of thrombosis (20% to 50%) and in the general population (4%).[19]

We describe a multiplex PCR assay to detect two common polymorphisms associated with hereditary thrombophilia. This multiplex PCR assay simply combines the original primers described for each mutation.[15,18] Each mutant allele is then detected in a single tube enzymatic digestion reaction which contains the Mnl I and Hind III restriction endonucleases. Ripoll et al have also described a multiplex PCR-mediated site-directed mutagenesis assay for the simultaneous detection of the factor V Leiden and the G20210A prothrombin mutations.[22] This assay engineers a Taq I restriction site in the PCR products for both genes.

In this study, we screened 303 individuals who were at clinical risk for developing thrombosis and who had prevously had factor V Leiden genotyping performed. For this patient population, we identified the heterozygous mutant prothrombin allele, G20210A, in 20/303 individuals (6.6%) and the homozygous mutant allele in 2/303 individuals (0.66%). Our findings are consistent with allele frequencies published in other studies for the prothrombin 20210 mutation. Cummings et al reported the G20210A allele to be present in 5.5% of anticoagulant clinic patients with confirmed deep vein thrombosis (DVT) or pulmonary embolism (PE), and Poort et al noted the G20210A allele to exist in 6.2% of consecutive unselected patients with a first episode of DVT.[14,15] Interestingly, neither of these groups found individuals homozygous for the G20210A allele. Poort et al did identify an individual homozygous for the mutant prothrombin allele who had a personal and family history of venous thrombosis, and in this cohort of familial thrombophilia patients, 18% were found to have the G20210A allele.[15]

It is apparent that the factor V Leiden mutation and the prothrombin genetic variant, G20210A, are common polymorphisms which are associated with an estimated five- to 10-fold and three-fold increased risk of venous thrombosis, respectively.[1,14,15,20,21] The G20210A mutation was also associated with elevated plasma prothrombin (factor II) levels, which in itself was found to confer increased risk for venous thrombosis.[15] The identification of the prothrombin gene G20210A mutation and the ability to simultaneously detect this mutation along with the more common factor V Leiden mutation provides further support for the genetic components of hereditary thrombophilia and their detection.

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Magnetic Resonance Imaging of a Mediastinal Ependymoma

DAVID P. NEUMANN, M.D., ROBERT J. SCHOLL, M.D., HELEN M. KELLET, M.D.,
AND RICHARD H. SIMON, M.D.

ABSTRACT—Ependymomas typically occur in the brain and spinal cord, and represent 5% and 16% of primary intracranial and spinal cord tumors respectively.[1] Ependymomas arising outside the central nervous systems are uncommon and when they do occur are usually seen in the sacrococcygeal region.[2] Other reported sites include the pelvis, spinal nerve roots,[3,4] and lung.[5] An extraspinal mediastinal ependymoma is a rare occurrence, with only two previously reported cases to our knowledge.[6,7] In both instances, the lesion arose in the posterior mediastinum, and were imaged with either chest radiographs alone[6] or chest radiographs and computed tomography.[7] In our case, plain radiography was followed by magnetic resonance imaging. This report documents the clinical, pathological, and magnetic resonance imaging findings in a case of a posterior mediastinal ependymoma. Primary mediastinal ependymomas are rare lesions that may be considered in the differential diagnosis of a posterior mediastinal mass.

Case Report

A 59-year-old woman was being seen by a neurosurgeon for lumbar spinal stenosis and had been scheduled for a spinal laminectomy. A preoperative chest radiograph (Fig. 1A) showed a 4-5 cm, noncalcified left paravertebral soft tissue mass at the level of the fourth thoracic vertebra. The patient was asymptomatic and had no history of cardiac or respiratory disease.

Magnetic resonance imaging (MRI) was performed on a 1.5T scanner (Magnetom Vision; Siemens, Erlangen, Germany) (Figs. 1B, C, D, and E), which demonstrated a bilobed, mixed-signal intensity mass measuring 4.2 by 3 by 2 cm in diameter in the left paraspinal region at T3–4, contiguous with the vertebrae and thoracic aorta. There was no visible extension into the adjacent neuroforamina or spinal canal. The superior component of the mass exhibited low-signal intensity on unenhanced T1-weighted imagies (T1WI), high-signal intensity on T2-weighted images (T2WI), and no appreciable enhancement following contrast administration, consistent with a cystic nature. The inferior component was intermediate in signal on unenhanced T1WI, mixed intermediate and high in signal on T2WI, and showed heterogeneous enhancement following contrast injection, indicating a solid constituency. A neurogenic tumor was suspected based on the lesion's posterior mediastinal location.

The patient underwent a left thoracotomy and the mass was completely excised. At surgery, a soft, partially cystic tumor was found; it was not adherent to surrounding bone, esophagus, or aorta, and no connection to the spinal cord or its coverings could be identified. True rosettes and pseudorosettes characteristic for ependymoma were among those features seen microscopically.[1]

Discussion

Central nervous system (CNS) ependymomas can arise from ependymal cells lining the ventricles, the central spinal canal, the choroid plexus, and remnant neural cells of the filum terminale. In adults, ependymomas account for 5% to 6% of all primary brain neoplasms,[4] whereas in children, they represent 10% of primary CNS tumors, most commonly in the fourth ventricle.[8] Ependymomas

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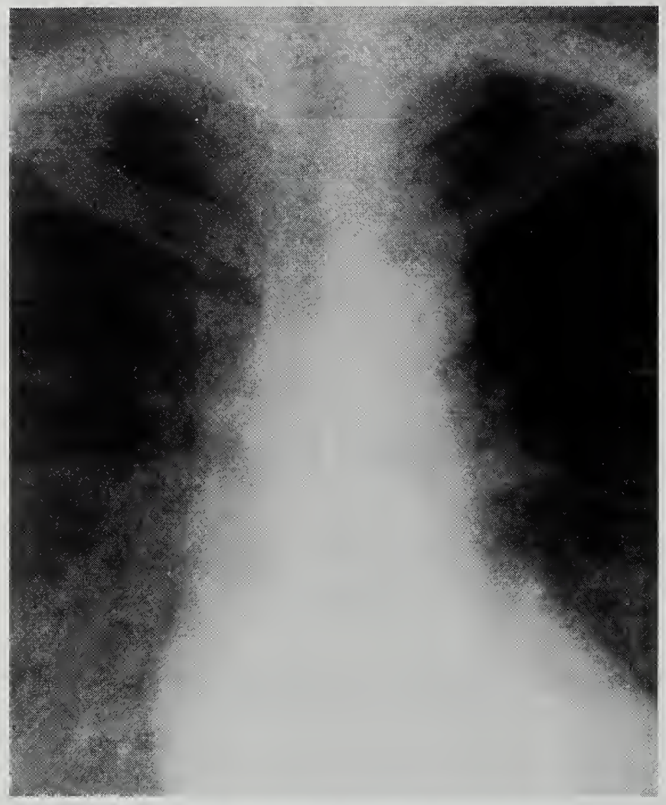


Figure 1.—59-year-old asymptomatic woman with mediastinal ependymoma. PA chest radiograph shows left superior mediastinal soft tissue mass partially visible above aortic arch.

are the most common primary intramedullary spinal tumor,[3] and make up 90% of tumors that arise near the cauda equina.[4] There is a bimodal age distribution with the first peak in children usually less than five years of age, and the another peak in the second to fifth decade of life.

Extraspinal ependymomas are more common in children than adults, typically arising from subcutaneous tissue posterior to the sacrum or in the presacral space posterior to the rectum.[2] Other reported sites of extraspinal ependymoma include the ovary,[9] mesovarium, and uterosacral ligament,[1] lung,[5] trigeminal nerve,[4] spinal nerve root,[3] omentum,[1] and the posterior mediastinum.[6,7]

Sacrococcygeal ependymomas are thought to arise from the coccygeal medullary vestige, a remnant of the primitive neural tube,[3] or from heterotopic ependymal cell rests, which are occasionally found in the sacrococcygeal tissues.[10] It is postulated that these extramedullary cells escape from the neural tube when there is failure of the primitive neural arch to close completely.[2] In fact, 20% to 30% of perisacral ependymomas are associated with spinal dysraphic lesions.[2]

Ependymomas arising from an ovarian and paraovarian location are thought to have a germ-cell origin and may be considered a monodermal teratoma.[7] A similar hypothesis has been put forth for mediastinal ependymomas, since primordial germ cells that give rise to germ-cell neoplasms are frequently encountered in this location.[9]

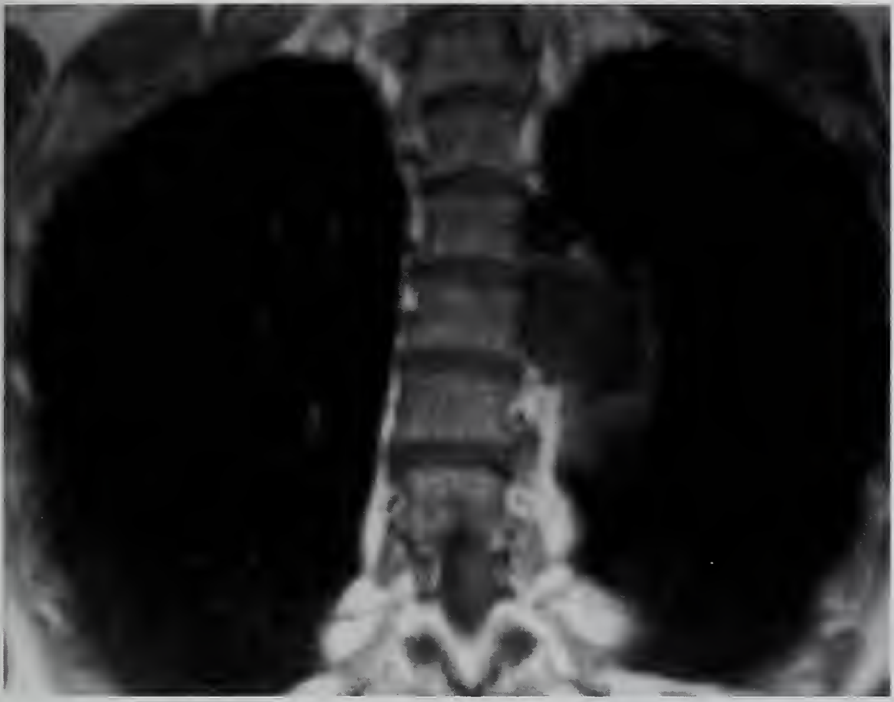
Extraspinal ependymomas are considered slow-growing low-grade malignancies. Metastatic disease is uncommon,[2] but most often occurs with CNS and sacral ependymomas.[9] Metastases to regional lymph nodes, lung, bone, liver, and peritoneum have been reported.[2] The possibility that our case represented a metastasis from an intracranial, intraspinal, or perisacral ependymoma was considered remote because of the lack of suggestive symptoms and normal MRI studies of these regions.

There have been two previously reported cases of mediastinal ependymoma, both of which arose posteriorly.[6,7] Doglioni et al reported the first case of a young adult woman without cardiorespiratory or central nervous system symptoms in whom a right posterior mediastinal mass was first discovered on routine chest radiography. No treatment was administered. The tumor was resected more than 30 years later because of worsening dyspnea. No demonstrable connection to the spinal cord or its integuments was found at surgery. This was confirmed at autopsy after the patient died of postoperative complications. Metastatic disease was also found in the patient's pleura and mediastinal lymph nodes. Of interest was the presence of both cystic and solid elements within the primary tumor, which were features present in our patient' lesion.[6]

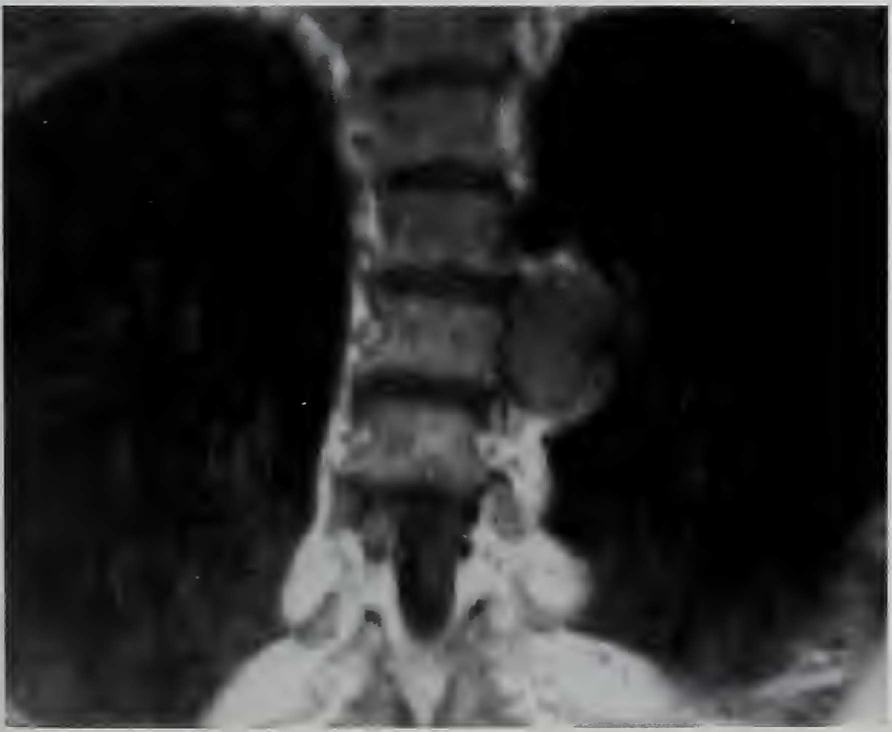
Nobles et al reported the second case in which a young adult female first presented with sharp pleuritic chest pain and shortness of breath. Admission chest radiographs revealed right upper lobe opacification and pleural effusion. Her condition deteriorated rapidly, with increasing dyspnea and hypotension requiring emergency surgery. A large necrotic, right posterior mediastinal mass was discovered that had ruptured through the parietal pleura, resulting in a large hemothorax. There was no connection found between the tumor and the spinal canal. That patient had an uneventful postoperative course.[7]

Long-term follow-up data are unavailable for mediastinal ependymomas. Local recurrence is common in extraspinal, extramediastinal ependymomas, and locally aggressive behavior has been described with one reported case of bony involvement and extensive destruction by an extraspinal ependymoma.[11] The mainstay of treatment is wide surgical excision, with repeated excision for local recurrences being fairly successful.[2] Ependymomas are radiosensitive, and focused-beam radiation is utilized for residual or unresectable tumors.[10] Chemotherapy is generally thought to be unsuccessful.[2]

An extraspinal ependymoma is a lesion that would not ordinarily be considered in the differential diagnosis of a mass in the posterior mediastinum. Neural tumors, how-



Figures 2a and 2b.—Coronal pre- (a) and postcontrast-enhanced (b) T1-weighted MR images demonstrate bilobed well-defined left paraspinal mass without enhancement in superior component and mild enhancement in larger inferior component.



ever do constitute the largest group and include ganglioneuromas and ganglioneuroblastomas, schwannomas, neurofibromas, and paragangliomas. Lymphadenopathy, foregut duplication cysts, neuroenteric cysts, paraspinal abcesses, and extramedullary hematopoesis are other diagnostic possibilities that may be considered depending on the clinical history and results of laboratory investigations.[12] A thymic carcinoid tumor and metastatic papillary carcinoma may resemble an ependymoma histologically and must be considered by the pathologist in the differential diagnosis.[6]

Summary

This report describes the magnetic resonance imaging features of an ependymoma arising in the mediastinum. To our knowledge, this is the third reported case of an ependymoma arising in this location but the first in which its appearance by magnetic resonance imaging has been demonstrated. The two previously reported cases of mediastinal ependymoma are briefly reviewed.

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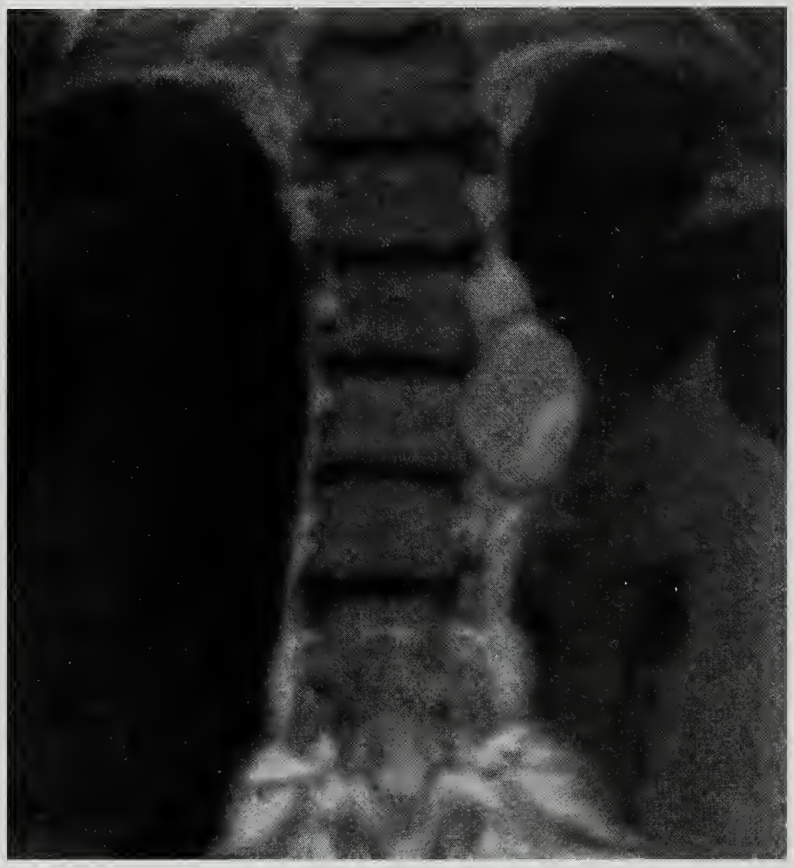

Figures 3a and 3b.—Coronal (a) and axial (b) T2-weighted images show high signal intensity in smaller superior component and areas of intermediate and high signal intensity in inferior component.

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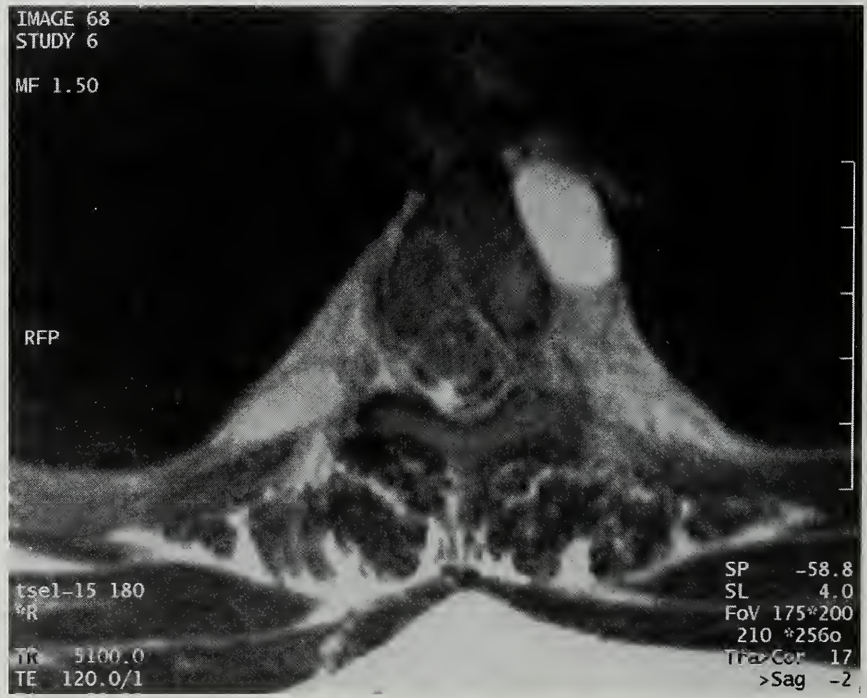

Cigarette Smoking in Connecticut: Home and Workplace Exposure

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ABSTRACT—Estimates of smoking prevalence, environmental tobacco smoke exposure patterns, and the effect of sociodemographic variables were obtained from a telephone survey of 596 randomly selected adults in Connecticut, aged 18 or older. Results of this study indicate that 21.5% of respondents smoked cigarettes, and the smoking prevalence of men was almost twice the rate of women. Smokers were disproportionately represented in lower education, income, and occupational status categories. Approximately 60% of respondents stated they do not allow smoking in their homes. Environmental tobacco smoke exposure in the home was inversely related to age, ($OR = .12, P < .0l$) and education ($OR = .23, P < .05$). Persons employed in crafts, trades, or general labor occupations were three times ($P = .01$) more likely to work in places which allowed smoking. Although Connecticut ranks among the top 10 states with the lowest cigarette smoking prevalence rates, continued antismoking efforts targeting lower socioeconomic groups will likely further reduce smoking and environmental tobacco smoke among adults and children.

Introduction

IN Connecticut cigarette smoking among adult residents is lower than the national average and it ranks among the top 10 states with the lowest smoking prevalence rates. Between 1985 and 1993, adult smoking in Connecticut declined 23%, exceeding the national decrease in smoking by 6%.[1] Despite these advances in reducing cigarette consumption, smoking and exposure to environmental tobacco smoke (ETS) remain major public health concerns.[2] A study by Adams noted that in 1989 there were 5,446 smoking-attributable adult deaths in Connecticut, 27% of which were caused by lung cancer. This study also estimated that smoking-related mortality and morbidity costs to the state have exceeded $944 million.[3]

This paper focuses especially the prevalence of cigarette smoking within homes in Connecticut because of the potential detriment to the health of nonsmokers, children, and adolescents.[4] Smoking-related illnesses, such as lower respiratory tract infections (eg, bronchitis, pneumonia), ear disorders, and asthma are exacerbated by ETS, particularly for children who are exposed to tobacco smoke at home.[5,6] Pirkle et al found in 1992 that, 43% of children two months to 11 years of age lived in homes with at least one smoker,[2] and a nationwide study found that approximately 15 million children and adolescents were exposed to ETS in their homes in 1996.[7]

The difficulty of achieving long-term abstinence from cigarette smoking increases the importance of implementing and monitoring practical restrictions on smoking within households to minimize exposure to children and other nonsmokers.[8] Another reason for restricting household smoking is to reduce the likelihood that children and adolescents will emulate the risk behavior of adult smok-

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ers. As noted by Flay, adolescent experimenting with tobacco leads to increased initiation because of exposure in their homes and greater social and physiological tolerance for cigarette smoke.[9]

We present the results of a 1997 telephone survey of smoking behavior and ETS among state residents. The results of this analysis may be instrumental in targeting specific adult population groups to reduce smoking prevalence and minimize ETS exposure in homes and at work.

Methods

Mathematica Policy Research, Inc., conducted a computer-assisted telephone survey with a representative sample of 596 Connecticut residents, 18 years of age and older, in the spring of 1997. The survey, which included questions about tobacco use and opinions about tobacco policy issues, was conducted under a contract between Mathematica and the Robert Wood Johnson Foundation to provide information to SmokeLess States grantees on public attitudes toward tobacco policy issues.

The sample of telephone numbers was designed so that all residential telephones, including new and unlisted numbers, had an equal chance of selection. Up to 20 telephone calls were made to sampled telephone numbers resulting in a response rate of 51%.

Data were weighted to correct for biases that could arise from groups of respondents being over or under represented. Sample weights were first computed to adjust for differences in the number of adults and residential telephones per household. Larger weights were assigned to households with substantial interruptions in telephone service to increase the representation of low income households less likely to have telephone coverage than the general population.

The primary dependent variables were current smoking status (defined as someone who has smoked 100 or more cigarettes and who presently smokes) and whether any smoking was permitted in individuals homes or at places of employment. Independent variables were age, gender, education, annual family income, occupational status, racially or ethnically classified social groups, and marital status. In addition, the effect of having lost a family member or a friend to a smoking-related illness was examined.

Data analysis was first performed using the Statistical Package for Social Services computer program to obtain descriptive statistics and for model building. Subsequently, the Survey Data Analysis program was employed to compute correct standard errors based on the sample design and to conduct multiple logistic regression (MLR) analyses.

Figure 1.—Sociodemographic Characteristics and Household Behaviors

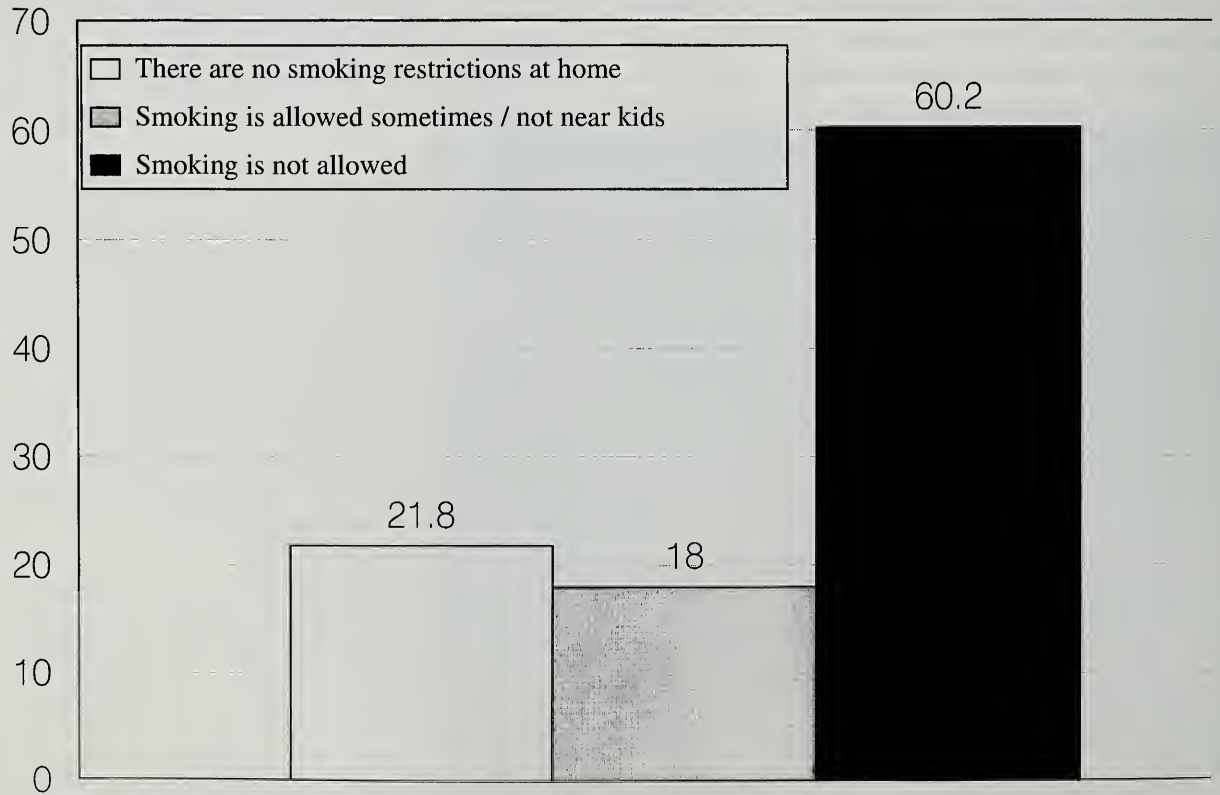

Table 1.—Sociodemographic Characteristics of Survey Respondents

	All respondents
Age categories (years)	
18–24	10.9
25–34	20.6
35–44	22.0
45–54	16.5
55 or older	29.9
Gender	
Male	47.5
Female	52.5
Education	
Less than high school	6.8
High school graduate	30.6
Some college	24.6
College graduate or more	38.0
Employment status	
Employed	62.9
Unempolyed	4.7
Not in the labor force	32.4
Lost a family member or friend to a smoking-related illness	42.9
Household income—1996	
Less than $20,000	13.4
$20,000 to $39,999	29.6
$40,000 to $49,999	12.1
$50,000 or more	45.0
Marital status	
Married/partnered	67.8
Unmarried/not partnered	32.2
Occupational status	
Professional/administrative/executive	31.9
Crafts/trades/factory work/service/laborer	17.4
Retired, student, homemaker, or other	35.0
Racial/ethnic classification	
White	88.2
Black, Hispanic, Asian, or other	11.8

Results

As shown in Table 1, the majority of respondents were white (88.2%), employed (62.9%), married or partnered (67.8%), and high school graduates or greater (93.2%). Fifty-seven percent of respondents reported an annual family income of at least $40,000. Approximately 30% were 55 years old or older.

The results indicated that 21.5% of adults in Connecticut smoked cigarettes and the largest age category of smokers (33.5%) was between 18–24 years old (Table 2). The smoking prevalence of men (27.8%) was almost twice that of women (15.5%). With respect to socioeconomic status (SES) indicators, smokers were disproportionately represented in the lower income, education, and occupational status categories. Approximately 18% of smokers reported that a family member or friend had died from a smoking-related illness.

Among smokers, almost 57% said they were planning to quit smoking cigarettes in the next six months. In this group of prospective quitters 72.6% were women compared to 56.8% men; 72.8% were smokers who had lost a friend or family member to cancer; and 68.4% married or partnered smokers compared to 53.8% unmarried or not partnered smokers.

As shown in Fig. 1, approximately 60% stated they do not allow smoking in their homes (including 6.3% of smokers). Respondents who did not restrict smoking in their homes were more likely to be nonhigh school graduates, unemployed, in blue collar and general labor occupations, and earning less than $40,000 annually. Among those respondents who allowed smoking in their homes at least "some of the time," two thirds (66.9%) reported being exposed to tobacco smoke. (Data not shown.) Racial or ethnic minority group respondents and older persons, (those 55 years and older) said they were less likely to permit smoking in their homes than whites and younger age groups. (Table 3).

While 68.6% of employed respondents stated that smoking was prohibited in any part of their place of employment, slightly more than one-quarter of respondents reported that their work setting continued to allow smoking in "some areas" (Table 4). Fewer than 6% of study subjects were currently working in places that allowed smoking in "all work areas." Of the 21% of respondents who reported being "exposed to smoke at the workplace," 61.8% of these persons were nonhigh school graduates. More than one-fourth also reported being exposed to ETS at home. (Data not shown.)

Multiple logistic regression (MLR) analyses were conducted to assess the relative effects of the independent variables on smoking, home and workplace exposure to second-hand smoke. Table 5 shows the adjusted odds ratios (ORs) of the independent variables and smoking prevalence. After adjusting for other variables in the MLR model, gender (OR =

Table 2.—Sociodemographic Characteristics and Individual Behaviors of Smoking and Intentions to Quit

	Smokers† (%)	**Planning to quit in the next six months (%)**
Age categories (years)		
18–24	35.5**	60.9
25–34	27.6	72.7
35–44	23.6	52.8
45–54	19.6	80.8
55 or older	11.6	43.2
Gender		
Male	27.8**	56.8
Female	15.5	72.6
Education		
Less than high school	39.8***	50.0
High school graduate	28.2	69.6
Some college	24.0	71.7
College graduate or more	11.1	45.2
Lost a family member or friend to a smoking-related illness	17.8	72.8
Household income—1996		
Less than $20,000	36.3*	70.2
$20,000 to $39,999	27.2	56.3
$40,000 to $49,999	21.2	50.0
$50,000 or more	16.0	69.7
Marital status		
Married/partnered	19.3	68.4
Unmarried/not partnered	25.4	53.8
Occupational status		
Professional/administrative/executive	14.8*	61.9*
Clerical/admin. assistant/sales/technical	20.5	88.9
Crafts/trades/factory work/service/laborer	37.6	71.5
Retired, student, or homemaker	19.6	40.6
Racial/ethnic classification		
White	21.9	58.9*
Black, Hispanic, Asian, or other	18.0	100.0
Total	**21.5**	**56.7**

†Percentages represent the proportion of persons in each demographic category who were current smokers. Current smokers were defined as persons who "have smoked at least 100 cigarettes in their lifetime" and "who currently smoke."

*$P \leq .05$ **$P \leq .01$ ***$P \leq .001$

0.39, $P < .001$), individual categories of age (OR = 0.24, $P < .01$), and education (OR = 0.15, $P < .001$) were significant predictors of smoking among Connecticut respondents. Specifically, women as well as persons 55 years and older were less likely to smoke than 18 to 24 year olds. College graduates relative to nonhigh school graduates were significantly less likely to smoke. Although the results were only marginally significant ($P = .07$) for racial and ethnic minority groups, they were less likely than whites (OR = .43) to smoke.

Table 3.—Sociodemographic Characteristics and Household Smoking Behavior

	There is at least one smoker in the household (%)	**Smoking is not allowed at home (%)**	**Smoking is not allowed near children or allowed sometimes (%)**	**There are no restrictions at home: smoking is OK (%)**
Age categories (years)				
18–24	41.8	57.9	20.3	21.8
25–34	17.9	61.1	22.9	16.0
35–44	21.0	61.9	11.7	26.4
45–54	27.7	55.5	17.4	27.0
55 or older	18.5	61.6	19.1	19.2
Gender				
Male	22.4	54.7	20.4	24.9
Female	23.3	65.2	15.8	19.0
Education				
Less than high school	49.1	33.1*	32.5*	34.3*
High school graduate	29.9	57.4	15.5	27.1
Some college	18.9	60.9	17.2	21.9
College graduate or more	15.2	66.9	18.1	14.9
Lost a family member or friend to a smoking-related illness	22.2	65.1*	18.9*	16.0*
Household income—1996				
Less than $20,000	28.3	49.7	22.6	27.8
$20,000 to $39,999	31.5	54.7	18.1	27.2
$40,000 to $49,999	18.0	62.6	24.2	13.2
$50,000 or more	18.2	65.0	16.4	18.6
Marital status				
Married/partnered	21.1	61.5	18.0	20.5
Unmarried/not partnered	26.9	57.5	18.9	23.7
Occupational status				
Professional/administrative/executive	16.6*	67.9	15.2	16.9
Clerical/admin. assistant/sales/technical	33.1	53.9	19.9	26.2
Crafts/trades/factory work/service/laborer	20.7	52.5	17.4	30.0
Retired, student, or homemaker	25.0	59.7	20.0	20.3
Racial/ethnic classification				
White	23.6	59.2	18.0	22.8
Black, Hispanic, Asian, or other	20.0	70.0	17.3	12.7
Total	**22.9**	**60.2**	**18.0**	**21.8**

*$P \leq .05$ **$P \leq .01$ ***$P \leq .001$ [Percentages are subject to rounding error.]

Education and gender were significant predictors of whether cigarette smoking was permitted in the home (Table 6). Highly educated respondents, particularly college graduates, (OR = .27, $P < .01$) were less likely to permit any form of cigarette smoking in their homes compared to nonhigh school graduates. In addition, women were more likely than men to prohibit household smoking (OR = .58 $P = .01$). As shown in Table 6, women compared to men (OR = .33, $P < .001$) were significantly less likely to report that smoking was permitted in all or some areas

Table 4.—Sociodemographic Characteristics and Workplace Smoking Policies

	Smoking is not allowed in any work areas (%)	**Smoking is allowed some work areas (%)**	**Smoking is allowed all work areas (%)**	**Respondent is exposed to smoke at work (%)**
Age categories (years)				
18–24	50.3	42.3	7.4	13.4
25–34	69.4	26.1	4.5	24.5
35–44	62.5	30.5	7.1	20.7
45–54	82.9	12.3	4.9	23.1
55 or older	70.3	25.9	3.8	16.9
Gender				
Male	59.1	33.0	7.9	20.3
Female	79.8	17.7	2.5	22.0
Education				
Less than high school	55.9	36.8	7.4	61.8
High school graduate	54.5	36.7	8.8	32.8
Some college	66.5	24.2	9.3	6.9
College graduate or more	79.8	19.3	0.9	20.7
Lost a family member or friend to a smoking-related illness	74.4	22.6	3.0	19.0
Household income—1996				
Less than $20,000	41.1	35.7	23.2	15.4
$20,000 to $39,999	61.0	36.4	2.6	22.0
$40,000 to $49,999	68.5	26.4	5.1	17.1
$50,000 or more	78.0	17.4	4.6	22.3
Marital status				
Married/partnered	71.6	23.0	5.4	19.8
Unmarried/not partnered.	62.2	32.3	5.4	24.7
Occupational status				
Professional/administrative/executive	81.1	16.9	2.0	19.4
Clerical/administrative assistant/sales/technical	71.4	25.8	2.9	16.3
Crafts/trades/factory work/service/laborer	44.7	41.4	13.9	34.9
Retired, student, or homemaker	41.2	50.0	8.8	18.7
Racial/ethnic classification				
White	70.8	23.2	6.0	20.9
Black, Hispanic, Asian, or other	56.7	40.8	2.5	23.0
Total	**68.6**	**26.0**	**5.5**	**21.2**

[Percentages are subject to rounding error.]

of their workplaces. Persons employed in crafts, trades, or general labor were three times more likely to work in places that allowed smoking(OR = 3.03, $P = .01$).

ETS exposure in the home was inversely related to age and education (Table 7). Older persons (ie, 45 years old or older, OR = .12, $P <.01$), individuals with some college (OR = .23, $P < .05$), and college graduates (OR = .13, $P < .01$) were significantly less likely to be exposed to ETS in their homes than their referent groups (ie, 18 to 24 year olds and nonhigh school graduates). Additional MLR analysis (Table 7) revealed that persons with a high-school education or greater (OR = .13, $P < .05$) were significantly less likely to be exposed to smoking at work.

Table 5.—Logistic Model of Current Smoking Status

	Adjusted logistic regression (O.R.)
Age categories (years)	
18–24	1.00
25–34	1.15
35–44	0.88
45–54	0.76
55 or older	0.24**
Gender	
Male	1.00
Female	0.39***
Education	
Less than high school	1.00
High school graduate	0.55
Some college	0.44
College graduate or more	0.15***
Lost a family member or friend to a smoking-related illness	0.65
Marital status	
Married/partnered	1.00
Unmarried/not partnered	1.29
Occupational status	
Professional/administrative/executive	1.00
Clerical/administrative assistant/sales/technical	1.24
Crafts/trades/factory work/service/laborer	1.31
Retired, student, homemaker, or other	1.59
Racial/ethnic classification	
White	1.00
Black, Hispanic, Asian, or other	0.43

Note: The independent variable was "current smoker" *vs* nonsmoker (never/former). The referent category was "smoker."
O.R. = Odds ratio. *$P \leq .05$ **$P \leq .01$ ***$P \leq .001$

Discussion

This study estimated that the smoking prevalence rate among Connecticut residents was 21.5% and was higher among 18 to 24 year olds, males, and those in the lower SES groups. These results are similar to the findings of other recent studies of smoking in Connecticut which reported rates of 21.9%[7] and 22.2%.[1]

Multivariate analysis showed that the strongest predictors of smoking were gender followed by age and education. Men were far more likely to be smokers than women. Though the adjusted MLR revealed inverse associations between age and education, it was only among the college educated and the elderly where the adjusted ORs in smoking prevalence were statistically significant.

According to the transtheoretical model of stages of behavioral change,[10] "planning to quit within the next six months" can be an important indicator of the ready-for-action stage of smoking cessation. Thus, the finding that almost two-thirds of current smokers were planning to quit within the next six months suggests that well-designed, community-based smoking intervention programs targeting these persons may be effective.

In 1997 the Connecticut organization entitled Mobilize Against Tobacco for Children's Health (MATCH) through a grant from the Robert Wood Johnson Foundation initiated the Healthy Homes project. Two of the major objectives of the Healthy Homes project are to heighten public awareness of the dangers of environmental tobacco smoke and to support public and social policies designed to protect Connecticut residents from ETS. Soliciting individual households to become a "Healthy Home" by not permitting cigarette smoking is a primary strategy to achieve these objectives. Initiatives that promote family or household-level as opposed to individual-level smoking cessation efforts would help increase the chances of success of projects such as Healthy Homes. Encouraging home smoking bans, refraining from smoking in the presence of children, and smoking outdoors only (rather than individual agreements on designated smoking rooms) have been shown to be effective family-based strategies.[8,11]

Despite the decline in smoking in the State and the finding that 60% of all homes in Connecticut do not permit smoking, this study found that 23% of respondents and 38% of nonsmokers reported ETS exposure in their homes. The groups most affected by ETS were 18 to 24 year old adults and those in lower SES groups. Wagenknecht et al also found a high rate of ETS exposure among younger nonsmokers, men, and nonhigh school graduates.[12] Health intervention programs and public policy changes should focus on targeting these adult population groups to reduce cigarette smoking and ETS both at home and at work.[13,14]

The limitations of this study include self-reported measures of smoking and indirect indicators of ETS exposure. Also, because of refusal to participate and other factors, sampling errors may be underestimated.

Connecticut, like most other states, has experienced a sizable reduction in cigarette smoking over the past 10 to 20 years, and this decline has resulted

Table 6.—Logistic Regression Models Of Respondents Who Allow Cigarette Smoking in their Homes and Who Work in Workplaces Where Smoking is Allowed

	Smoking is allowed at home (O.R.)	**Smoking is allowed at work (O.R.)**
Age categories (years)		
18–24	1.00	1.00
25–34	1.19	0.91
35–44	1.11	1.44
45–54	1.48	0.65
55 and over	0.89	0.79
Gender		
Male	1.00	1.00
Female	0.58**	0.33***
Education		
Less than high school	1.00	1.00
High school graduate	0.41	1.05
Some college	0.35*	0.82
College graduate or more	0.27**	0.57
Occupational status		
Professional/administrative/or executive	1.00	1.00
Clerical/admintrative support/sales/technical	1.90	1.58
Crafts/trades/factory work/service/laborer	1.51	3.03**
Retired, student, or homemaker	1.56	6.87
Lost a family member or friend to a smoking-related illness	0.70	0.74
Marital status		
Married/partnered	1.00	1.00
Unmarried/not partnered	1.21	1.38
Racial/ethnic classification		
White	1.00	1.00
Black, Hispanic, Asian, or other	0.56	1.55

Note: The referent categories are "smoking is allowed at home" and "smoking is allowed at work."
OR= Odds ratios. *$P \leq .05$ **$P \leq .01$ ***$P \leq .001$

in a decrease in smoking-related illnesses in the state. This reduction in smoking is attributed largely to the resolve and commitment of the public health community and health practitioners to promote smoking prevention and cessation through school-based programs, health policy and legislative initiatives, changes in social norms regarding smoking, and community intervention programs. Continued support and expansion of these antismoking efforts, such as the Healthy Homes project, will likely further reduce cigarette smoking and ETS exposure among children and adults in Connecticut.

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Table 7.—Logistic Regression Models of Respondents Who Were Exposed to Cigarette Smoke

	At their homes (O.R.)	**At their workplaces (O.R.)**
Age categories (years)		
18–24	1.00	1.00
25–34	0.26	3.66
35–44	0.29	3.31
45–54	0.12**	4.32
55 and over	0.09***	1.27
Gender		
Male	1.00	1.00
Female	0.90	1.39
Education		
Less than high school	1.00	1.00
High school graduate	0.33	0.13*
Some college	0.23*	0.03***
College graduate or more	0.13**	0.08**
Occupational Status		
Professional/administrative/or executive	1.00	1.00
Clerical/admintrative support/sales/technical	1.49	0.79
Crafts/trades/factory work/service/laborer	0.65	1.57
Retired, student, or homemaker	1.23	1.00
Have you ever lost a family member or friend to a smoking-related illness?	0.60	0.83
Marital status		
Married/partnered	1.00	1.00
Unmarried/not partnered	0.54	0.88
Racial/ethnic classification		
White	1.00	1.00
Black, Hispanic, Asian, or other	0.48	1.22

Note: The referent categories are "respondent is exposed to smoke at home" and "respondent is exposed to smoke at work."
OR= Odds Ratios. *$P \leq .05$ **$P \leq .01$ ***$P \leq .001$

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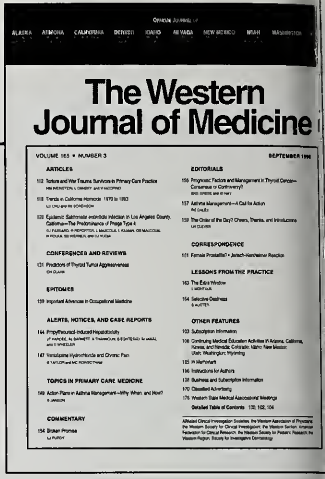

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Important Advances in Clinical Medicine

Urology

DANIEL A. NACHTSHEIM, M.D., Section Editor

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in urology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in urology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Urology of the California Medical Association, and the summaries were prepared under the direction of Dr Nachtsheim and the Panel.

Best Screening Tests for Prostate Cancer

IN 1998 alone, about 500 men will be diagnosed with prostate cancer every day, and approximately 39,000 will die of the disease. Recognizing that population screening for prostate cancer using PSA and DRE have neither been proven or disproven to be effective to reduce the morbidity and mortality of the disease, authorities now recommend that physicians and health-care organizations provide the pros and cons and let the well-informed patient decide. Just as it would be wrong to mandate screening, it would be.just as wrong not to offer the option of early detection tests for prostate cancer.

Potential screening tests for prostate cancer include the digital rectal exam (DRE), the seromarkers prostate specific antigen (PSA) and prostatic acid phosphatase (PAP), and transrectal ultrasound of the prostate (TRUS). The DRE remains an important method of detecting many prostate cancers that may be missed with a PSA test. The PSA test is a simple blood test. Although PSA and PAP are both seromarkers for prostate cancer, the latter is inappropriate for use in screening because levels of PAP often do not become elevated until the disease has reached an advanced stage. Therefore, PAP should be used only for staging the disease after it has been diagnosed and never for screening. Transrectal ultrasound of the prostate is not a suitable screening test. It cannot differentiate many small cancers from surrounding noncancerous prostate tissue, but it is appropriate for directing biopsies in men who have abnormal findings on DRE or PSA testing.

The PSA test has been approved by the U.S. Food and Drug Administration as a method of screening for prostate cancer, but it is not perfect. Although a PSA level > 4.0 ng/mL is considered abnormal, men with a level of between 4.1 and 10.0 ng/mL, often considered the "grey zone," will have prostate cancer detected about one-third of the time. In men with a PSA level > 10.0 ng/mL, approximately two-thirds will have cancer. The specificity is only 59% for all PSA levels > 4.0 ng/mL. Sensitivity is also suboptimal, as levels > 4.0 ng/mL will detect prostate cancer in only 79% of cases. In other words, the use of this cutoff point will miss 21% of patients with prostate cancer who have PSA levels of < 4.0 ng/mL.

Several recent refinements may improve the clinical utility of PSA. Measurements of PSA density are based on the ratio between the PSA level and the prostate volume (as measured on transrectal ultrasound). A PSA density value less than 0.15 in a patient suggests that benign prostatic hypertrophy (BPH) alone may be responsible for

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the PSA elevation and a biopsy may not be indicated if the digital rectal examination is normal. This method helps adjust for the proportion of PSA elevation that may be related simply to BPH. However, the reliability of the method depends on reproducible measurements of prostate volume by transrectal ultrasound.

Assessments of PSA rate of change or PSA velocity are useful for men who undergo screening over a period of time. A PSA increase > 0.75-0.80 ng/mL over a one-year period may indicate an increased probability of prostate cancer and may signal the need for further evaluation. On the other hand, recent research has suggested that men who start with a very low PSA value less than 2.0 ng/mL have a very low probability of jumping to a worrisome PSA over one year, and that every-other-year testing may be acceptable for this group. Some, but not all, studies have suggested that digital rectal examination, ejaculation, or bicycle riding may raise the PSA level unrelated to prostate cancer leading to a false positive test. In a man with mildly elevated PSA level, these things should be avoided for 48–72 hours prior to repeat testing.

Recently, the use of age-specific reference ranges (ASRRs) has generated particular interest. These ranges, derived from control populations of men without prostate cancer, adjust for the increases in prostatic hyperplasia and PSA levels that occur with aging. Levels above the 95th percentile of these normal men by decade of age are considered abnormal. Newer data have suggested that different racial groups may have different ASRRs. For instance, ASRRs are lower in Japanese men than in American men. Also, African American men with newly diagnosed prostate cancer have higher serum PSA values than do whites, even after correction for stage, grade, and tumor volume.

Aside from PSA-density, rate-of-change and ASRR, another tool—the “free” PSA—has recently been FDA-approved. Over the last few years, researchers discovered that PSA protein may be free or bound to other proteins in the bloodstream. Most PSA is complexed to other proteins, most commonly a protein called alpha-1 antichymoltrypsin (ACT). The percentage of free, complexed, and total PSA and their ratios are different between men who do and do not have prostate cancer and these differences can be exploited to screen for prostate cancer. The most useful ratio identified to date is the percentage of free PSA to the total PSA. Although studies are still being conducted, it appears that the lower the percent of free PSA, the higher the risk of prostate cancer.

With the aging of the U.S. population and the high incidence of prostate cancer, the debate regarding the early detection of the disease continues. Although randomized clinical trials have yet to prove or disprove the efficacy of prostate cancer population-based screening, patients should be counseled regarding the pros and cons of early detection. The PSA and DRE tests are accepted case finding tools. Many urologists favor a strategy of annual PSA blood tests and DREs for men > 50 years old. Annual assessments should begin at age 40 for African American men and those who have a family history of prostate cancer. New “PSA-tools” such as age- and race-specific reference ranges and free-PSA seem to make the testing more reliable. The relationships between testing, treatment, and outcome need further clarification.

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Urolithiasis

RENAL and ureteral stones are frequently encountered in industrialized countries, in contrast to bladder calculi noted in developing countries and ancient times. Most ureteral calculi are passed spontaneously. Extracorporeal shock wave lithotripsy (ESWL), ureteroscopy, and percutaneous nephrolithotomy are saved for patients in whom spontaneous passage has failed. Dietary modifications and medical treatment can reduce recurrent urinary stone disease substantially. Despite improved surgical treatment, 50% of patients will have recurrent stones within five years if no metabolic intervention is undertaken.

Patients usually present with acute flank pain associated with nausea and vomiting. Chronic back pain, hematuria and incidental discovery with radiographic imaging are other frequent reasons for referral to urinary stone centers. Eighty-five percent of patients with urinary calculi will have either micro or gross hematuria. A complete blood count is warranted for patients who have calculi and fever. Serum electrolytes and creatinine should be obtained. A plain abdominal radiograph (KUB) is the best initial imaging modality; it helps pinpoint the location of the calculus, since 85% to 90% of urinary tract calculi are radio-opaque. The KUB may be followed by directed renal sonography or intravenous pyelography to confirm stone location and guide management. Where available, noncontrast helical CT scanning is becoming the examination of choice for acute renal colic. It is safe, rapid, and has shown 97% sensitivity and 96% specificity in detecting renal and ureteral calculi.

Acute renal colic is treated initially with analgesics and hydration to maintain a euvolemic state. The majority of ureteral calculi less than 6 mm in size will pass with this management. Pain, persistent vomiting, fever, or failure of stone progression requires intervention.

A medical evaluation for patients who form stones more than once should be initiated after the acute stone episode is resolved. The stone should be retrieved and analyzed. Serum electrolytes, creatinine, calcium, phosphate, uric acid, and parathyroid hormone (PTH) should be obtained. A 24-hour urine collection including urine volume, pH, specific gravity, calcium, creatinine, citrate, oxalate, phosphate, uric acid, and sodium will direct medical therapy.

Stone analysis, revealing either calcium or noncalcium calculi, guides medical management. Most stones are composed of calcium oxalate. Pure calcium phosphate calculi may indicate the presence of distal renal tubular acidosis (RTA) or primary hyperparathyroidism. Hypokalemia and decreased serum bicarbonate with a fasting urinary $pH > 5.5$ confirms the diagnosis of distal RTA (type 1). Elevated serum PTH, calcium, and decreased serum phosphorus characterize patients with primary hyperparathyroidism.

Calcium urolithiasis can be subdivided into hypercalciuric and normocalciuric states. The hypercalciuric metabolic defects may be subclassified as absorptive, resorptive, and "renal leak."

There are three classes of absorptive hypercalciuria: diet independent (type I, diet dependent (type II), and renal phosphate leak (type III). All are characterized by >250 mg of calcium in a 24-hour urine specimen. Type I patients have elevated urine calcium during both high and low calcium intake. Serum calcium and PTH are normal. Thiazide diuretics or cellulose phosphate are effective treatments and decrease urinary calcium excretion. Type II hypercalciurics exhibit hypercalciuria only during increased calcium dietary intake. Therapy is directed at decreasing dietary calcium by about 50% to approximately 400 mg/day; over the long term bone density is stable. Type III absorptive hypercalciuria is secondary to a renal phosphate "leak." The low serum phosphate stimulates vitamin D and subsequent absorption of phosphate and calcium. Treatment with bioavailable phosphate (neutral orthophosphate) is effective.

Resorptive hypercalciuria is due to primary hyperparathyroidism and is treated with surgical removal of the parathyroid adenoma.

Renal "leak" hypercalciuria is caused by defective tubular reabsorption of calcium. Secondary hyperparathyroidism is often noted. This condition is successfully treated over the long term with thiazides.

Hyperuricosuria, hypocitraturia, and hyperoxaluria comprise the normocalciuric conditions associated with calcium lithiasis. Hyperuricosuria may be associated with gout, myeloproliferative states and malignancy but is most frequently due to dietary overindulgence. Monosodium urate crystals act as nidi for calcium oxalate stones by heterogeneous nucleation. Decreased sodium intake is critical for management, as with hypercalciuric states. If reduced intake of dietary purines is unsuccessful, allopurinol is usually effective.

Hyperoxaluria is most commonly due to chronic diarrheal states such as inflammatory bowel disease. Increased fecal fats bind to intraluminal calcium, thus calcium is unavailable to bind to oxalate which is readily absorbed. Mild cases may be controlled with intake of calcium rich foods with meals to bind dietary oxalates. More severe cases may require calcium containing antacids at mealtime.

Citrate is a potent inhibitor of calcium lithiasis, acting by complexing with urinary calcium in solution. Low urinary citrate (< 320 mg/day) is associated with conditions resulting in a metabolic acidosis (ie, chronic thiazide use, renal tubular acidosis, diarrhea). These patients are successfully treated with citrate supplements, such as potassium citrate or naturally occurring citrate found in lemonade.

The three most common noncalcium stones are uric acid, struvite, and cystine. Less common stones may be matrix, xanthine, or drug related (triamterene and indinavir).

Uric acid calculi are relatively radiolucent and patients consistently have urinary $pH < 5.5$. The stones may be dissolved with urinary alkalinization (oral Kcitrate or K bicarbonate) at a rate of 0.5 cm per month. Solubility of uric acid rapidly rises above pH 6.0. As with all stone formers, patients should be encouraged to maintain a urinary output of 1.5–2.0 liters per day. They are encouraged to drink fluid with meals, two hours after each meal, and prior to bedtime, adequate enough to awaken the patient to void.

Struvite stones (magnesium ammonium phosphate) occur in the presence of infection with urea-splitting organisms and are seen most commonly in women. They frequently present with non- *E. coli* recurrent urinary tract infections. Sterilization of the calculi using antibiotics is futile; surgical removal of the infected stones remains the cornerstone of treatment. A full metabolic evaluation is necessary because most stones are of mixed composition and metabolic defects may be identified.

Cystinuria is a hereditary defect affecting the transport of dibasic amino acids in the small bowel and renal tubules. Elevated levels of urinary cystine precipitate at normal urinary pH (5.8–6.0); the solubility of cystine increases above pH 7.5. Treatment centers on urinary alkalization, hydration, and sulfhydryl binding agents such as alpha mercaptopropionyl glycine (Thiola).

Urinary stone disease is common and is usually characterized by acute onset of severe colic. Stone size does not correlate with the severity of symptoms. Frequently, small ureteral stones are most painful. Although recurrences often mark the course of this disease, dietary manipulation and medical therapies can result in stone prevention and avoidance of complications.

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Epidemiology of Prostate Cancer

IN 1996 alone, 317,000 men were diagnosed with carcinoma of the prostate. The overall incidence showed a slight rise in 1989 followed by a sharp rise in 1991, peaking in 1992–93. Since then, there has been a gradual decline. The observed increase is a response to an aggressive nationwide prostate screening program.

It has long been known that the incidence of prostate cancer increases with age. Of major significance and interest now are the varying rates of incidence of prostate cancer according to racial distribution. The incidence is highest among African-Americans at 188 per 100,000 person-years, intermediate among whites at 139 per 100,000 person-years, and lowest among Asians at 39 per 100,000 person-years for Japanese and 28 per 100,000 person-years for Chinese. Of significance is the observation that Asians living in the United States have a higher incidence of prostate cancer than those residing in their country of origin, but still lower than whites and African-Americans.

In addition to a higher incidence, it appears that African-American men with prostate cancer have a higher grade and larger cancer volume when compared to Caucasian men. They may also have a significantly higher prostate specific antigen (PSA) level after radical prostatectomy, suggesting a greater residual tumor burden. Some feel that these data argue for aggressive and early detection programs among African-American men, although the outcome of treatment is still being evaluated.

Family history of prostate cancer is now a recognized risk factor for prostate cancer.The relative risk for a man developing it depends on the number of affected relatives (about 1.4 with one affected first degree relative and over three with more than one.) Current data suggest that familial prostate cancer may be a more aggressive type of cancer. Patients with familial prostate cancer have a worse outcome after radical prostatectomy than patients with nonfamilial prostate cancer. The poor result is primarily related to a higher distant relapse rate, suggesting that familial cancer is biologically more aggressive. Recent reports confirm the existence of a rare autosomal dominant prostate cancer susceptibility gene dubbed "HPC1" for "hereditary prostate cancer 1." Some feel these data argue for aggressive early screening for men with family history of prostate cancer, although outcome studies have not been completed.

In addition to the racial and familial risk factors associated with prostate cancer, several other risk factors are being hotly pursued, but are not established. Factors being evaluated include cigarette smoking and consumption of dietary fat, tomatoes, and supplemental selenium. Other areas of interest include association with farming and history of vasectomy.

As cigarette smoking is implicated with lung cancer, it is also being investigated for its relationship with prostate cancer. Higher death rates from prostate cancer in current cigarette smokers suggests that smoking may adversely affect survival in prostate cancer patients, however.

Dietary factors have been correlated with prostate cancer. Early studies support the hypothesis that high dietary fat intake is correlated with prostate cancer. Dietary fat intake was observed primarily with animal fat and meat consumption rather than vegetable fat consumption. Recent reports, however, tend to refute the previously asserted association, finding no link between dietary fat, especially animal sources, with risk or mortality of prostate cancer. Epidemiologic studies suggest high consumption of tomatoes or supplemental selenium may protect against prostate cancer. These findings need confirmation before dietary changes are made.

Recent reports indicate a positive correlation between prostate cancer and farming. Authors speculate that hormonally active agricultural chemicals are potential risk factors among farmers.

The suggestion that vasectomy may increase the risk of prostate cancer is being disputed by evaluating confounding factors. For example, the odds ratio estimate for prostate cancer associated with vasectomy tended to increase among men with such known risk factors as a father and brother with prostate cancer. Any increased risk may be related to detection bias or differential participation rates due to both vasectomy status and a family history of prostate cancer.

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Sildenafil: A Milestone in the Treatment of Impotence

WITH an estimated 18–30 million American men who experience some degree of erectile dysfunction, it is not surprising that sildenafil, the first effective oral treament agent, released under the trade name Viagra by Pfizer Co. in April 1998, has been the fastest selling drug in pharmaceutical history. Sildenafil is an inhibitor of phosphodiesterase type 5 (PDES). When initially investigated in patients with cardiac disease to promote vasodilatation, many reported improved erectile response.

Erections occur through sexual stimulation of the parasympathetic nervous system leading to release of the neurotransmitter nitric oxide, a powerful vasodilator derived from the endothelial cells lining the penile spaces—the corpus cavernosum. Nitric oxide then produces cyclic GMP which causes the smooth muscle of the corpus cavernosum to relax and fill with arterial blood, creating the erection. Pressure from these expanding spaces occludes veins against the tunica albugenia, surrounding the erectile tissue and leading to sustained erection.

Sildenafil works by blocking the enzyme, phosphodiesterase 5, which breaks down cyclic GMP, leading to higher sustained levels of cyclic GMP and relaxation of the smooth muscle spaces of the penis, and thereby amplifies sexual stimulation. Sildenafil has no direct effect on increasing libido but may enhance the sexual experience by decreasing performance anxiety caused by anticipated failure.

Available in 25, 50, and 100 milligram tablets,(a 50 mg tablet is the most common dose), sildenafil is taken about one hour prior to sexual activity to allow for absorption. Effects last three to five hours. About 70% of men with erectile dysfunction experience improved erections. Most side effects are attributable to vasodilatation: headache and flushing (10%). Additionally, about 3% of patients experience mild and transient visual effects—predominantly color tinge, but also light sensitivity—a pharmacological response thought to be related to sildenafil's weak inhibition of PDE6, found in the retina. The most serious side effect is hypotension, which may be amplified by concomitant use of nitrates; therefore, use with nitroglycerin or other nitrates is contradicted. Deaths reported to date in patients taking sildenafil do not appear to be greater than the same cohort of cardiac patients not taking the drug. The Federal Drug Administration is investigating all reported deaths.

Sildenafil is not present in significant amounts in the ejaculate and it therefore poses no risk to conception or pregnancy in women whose partners take the drug.

Although with sildenafil oral pharmacotherapy becomes the front line treatment in the "goal-orientated" approach to treatment, underlying medical conditions such as hypogonadism, diabetes mellitus, and hypertension also need to be addressed in men with impotence.

What about women? Early reports suggest that sildenafil can increase lubrication and vascular vaginal engorgement in women, but safety and efficacy have not been established, and sildenafil is not currently recommended for use in women. Several studies are underway, however.

Other drugs expected to be available shortly include phentol amine mesulate (Vaso-Max™ by Zonagon Corp.), an apha-blocker reported to be effective in 40% of men by increasing penile arterial blood flow. In addition, a refined form of apomorphine delivered by sublingual administration will be available. Apomorphine does not affect cyclic GMP, but rather acts as a dopamine agonist, modulating erections through the nervous system. Early reports suggest a 50% effectiveness rate. Finally, research efforts will inevitably produce other phosphodiesterase inhibitors similar to sildenafil.

What about penile injections and the other forms of impotence treatment? The proven success of penile injection pharmacotherapy with agents such as prostaglandin E, and combinations as "tri-mix" (prostaglandin, papaverine and phentolamine) remains durable, and makes this approach still reasonable and cost effective. A difference in the mechanism of action of the injectables from sildenafil allows for success of these agents where sildenafil may fail. Intra-urethral insertion of prostaglandin E pellets (M.U.S.E by Vivus corp) remains an option for 10% to 20% of men. Yohimbine hydrochloride tablets (Yocon), 5.4 mg three times a day, are effective for 5% to 15 % of men.

Mechanical devices remain available in the form of the vacuum erection device and the surgically inserted penile prosthesis. It is currently unclear whether sildenafil will be an enhancement to these mechanical aids.

If medications, mechanical devices, or counseling are not effective, then referral to a urologist is appropriate.

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MORBIDITY AND MORTALITY WEEKLY REPORT

Civilian Outbreak of Adenovirus Acute Respiratory Disease—South Dakota, 1997

ADENOVIRUSES are human pathogens that commonly infect the respiratory and gastrointestinal tracts.[1] Adenovirus infections are endemic, particularly among children, but also may cause epidemics of pharyngoconjunctival fever, keratoconjunctivitis, gastroenteritis, and acute respiratory disease (ARD) among military trainees. Outbreaks of ARD among adults in the civilian sector are rare.[2] In March 1997, an outbreak of acute respiratory disease (ARD) caused by adenovirus serotype 11 occurred among students at a job training facility in South Dakota. This report summarizes the epidemiologic and clinical features of this outbreak and discusses the change in availability of adenovirus vaccines for military use.

The facility provides high school education and vocational training for 240 persons aged 16–21 years. New students matriculate year-round at two-week intervals and remain for approximately one to two years. All students live on campus in one of four barracks-style dormitories (three for males and one for females). Sixty students are housed in each dormitory, with six to 10 persons per room sleeping in bunk beds. Students share a common dining hall. Routine medical care is provided by an infirmary nurse, who refers more severe illnesses to visiting physicians or local hospitals. Hospitalization discharge summaries are forwarded to the infirmary nurse.

Following the outbreak, a chart review was conducted at the facility's infirmary by the infirmary nurse. A case of lower respiratory tract infection (LRTI) was defined as physician-diagnosed pneumonia, an abnormal chest radiograph, or rales or wheezing on pulmonary auscultation in any student. A case of upper respiratory tract infection (URTI) was defined as coryza and sore throat without LRTI in any student. A case of ARD was defined as either URTI or LRTI in any student.

During March 8–28, a total of 146 (61%) students were diagnosed with ARD (Fig. 1); 103 (71%) had URTI; and 43 (29%) had LRTI. The ARD attack rate was higher among males than females (69% *vs* 37%, respectively, $P<0.01$). Although students with URTI and LRTI were similar in age and sex, frequencies of associated signs and symptoms differed between the two groups (Table 1). Students with URTI were more likely than students with LRTI to have headache. Students with LRTI were more likely to have fever ≥101 F (≥38.3 C), pleuritic chest pain, shortness of breath, lymphadenopathy, vomiting, conjunctivitis, and dysuria (all P values <0.05). Students with LRT had higher fevers than students with URTI (median maximum temperatures: 103 F (39.4 C) *vs* 102 F (38.9 C), $P<0.001$). Five (12%) of 43 students with LRTI were hospitalized for three to seven days each. One ill student with a poorly controlled seizure disorder suffered a respiratory arrest and required intensive care. Staff members at this facility also reported ARD symptoms during this time period.

Throat swab specimens were collected from seven ill students and inoculated into RMK and A549 cells. Six specimens yielded adenovirus, identified as subgenus B by the polymerase chain reaction assay, and as adenovirus 11 by microneutralization assays.[2–4] The sequences of a one kilobase region of the fiber gene were identical for all isolates, suggesting a single outbreak strain.

Reported by: O. Four Bear, Box Elder Job Corps, Nemo; L.M. Schaefer, L.M. Kellen-Anderson, S.L. Parker, D.V.M., State Epidemiologist, South Dakota Department of Health, D.P. Schnurr, Ph.D., Viral and Rickettsial Diseases Laboratory, California Department of Health Services. J.C. Gaydos, M.D., Division of Preventive Medicine, Walter Reed Army Institute of Research, Washington, DC. Respiratory and Enteric Viruses Branch, Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, CDC.

Editorial Note: Although adenovirus-associated ARD outbreaks among military training populations are well-described, they have not been recognized among college students or other young adults in the civilian sector.

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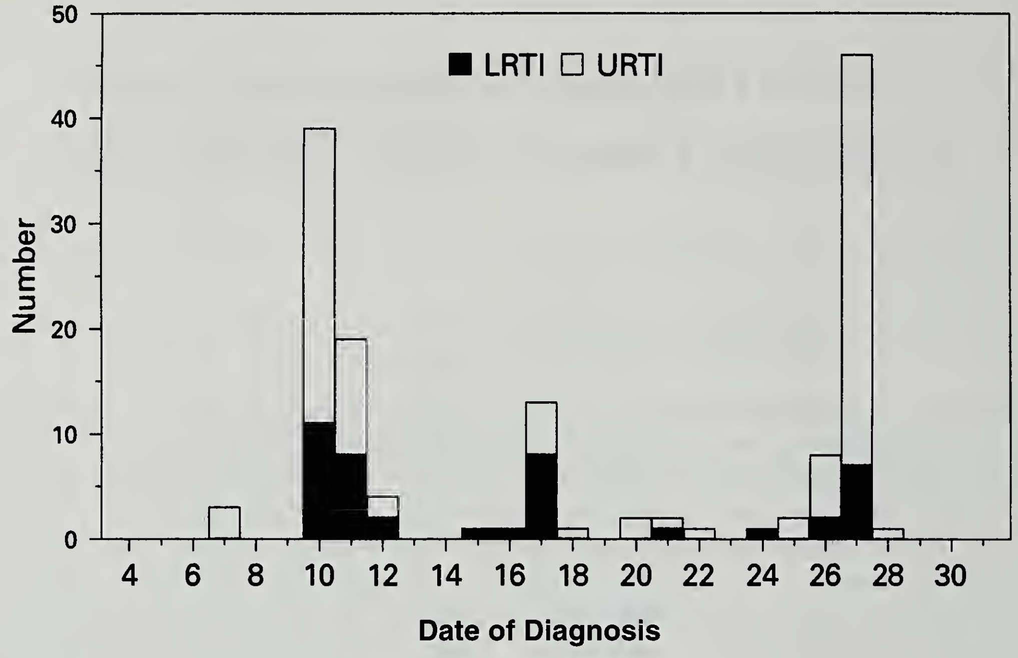

*A case of LRTI was defined as physician-diagnosed pneumonia, an abnormal chest radiograph, or rales or wheezing on pulmonary auscultation in any student. A case of URTI was defined as coryza and sore throat without LRTI in any student.

Figure 1.—Cases of lower respriatory tract infection (LRTI) and upper respirator tract infection (URTI)* among students at a job-training facility, by date of diagnosis—South Dakota, March 4–31,1997

Table 1.—Clinical features of students with acute respiratory disease (ARD), upper respiratory tract infection (URTI), and lower respiratory tract infection (LRTI)*—South Dakota, 1997

	ARD (n=146)		**URTI (n=103)**		**LRTI (n=43)**	
Clinical features	**No.**	**(%)**	**No.**	**(%)**	**No.**	**(%)**
Coryza	140	(96)	103	(100)	37	(86)
Sore throat	139	(95)	103	(100)	36	(84)
Headache	138	(95)	102	(99)	36	(84)
Fever ≥101 F (≥38.3 C)	76	(52)	36	(35)	40	(93)
Lympadenopathy	34	(23)	12	(12)	22	(51)
Shortness of breath	34	(23)	0	—	34	(79)
Wheezing	34	(23)	0	—	34	(79)
Conjunctivitis	30	(21)	13	(13)	17	(40)
Pleuritic chest pain	26	(18)	0	—	26	(61)
Vomiting	22	(15)	4	(4)	18	(42)
Rales	22	(15)	0	—	22	(51)
Dysuria or hematuria	3	(2)	0	—	3	(7)
Abnormal chest radiograph	28	(19)	0	—	28	(65)

*A case of LRTI was defined as physician-diagnosed pneumonia, an abnormal chest radiograph, or rales or wheezing on pulmonary auscultation in any student. A case of URTI was defined as coryza and sore throat without LRTI in any student. A case of ARD was defined as either URTI or LRTI in any student.

However, the setting of this outbreak of adenovirus ARD is similar to settings of previous military ARD outbreaks. In both settings, young adults live in crowded conditions, and new groups of potentially susceptible persons are introduced regularly. This outbreak differed from military outbreaks because most adenovirus-associated ARD outbreaks among U.S. military trainees are associated with adenoviruses 4 and 7. Adenovirus 11 is most commonly recognized as a cause of hemorrhagic cystitis, acute hemorrhagic conjunctivitis, and illnesses among immunocompromised persons[1,5] and has rarely been associated with ARD in military trainees or in any other immunocompetent adult population.[6]

Outbreaks of adenovirus-associated ARD were common among U.S. military trainees before the 1970s, when routine vaccination of this group with oral vaccines against adenovirus serotypes 4 and 7 was instituted.[7,8] Although these vaccines were highly effective, their manufacture has been discontinued.[9] Residual supplies of the vaccines will probably be exhausted in 1999, at which time large ARD outbreaks in military settings are expected, primarily in winter months.[9] This outbreak underscores that adenoviruses can cause outbreaks of ARD among young adults, persons living in crowded conditions, and military recruits.

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Vitamin Supplements

Many patients ask their physicians whether they should take vitamins. In recent years, more data have become available on the risks and benefits of taking vitamin supplements.

VITAMIN E—The primary food sources for vitamin E are vegetable and seed oils; the usual diet in the U.S.A. provides about 15 IU/day. Vitamin E in food, which is mostly gammatocopherol, acts as an antioxidant. Vitamin E in supplements is mostly alpha-tocopherol, which *in vivo* may block the antioxidant activity of gamma-tocopherol and have a prooxidant effect (Christen S, et al: *Proc Natl Acad Sci* USA 1997; 94:3217). High doses of vitamin E may interfere with vitamin K metabolism and platelet function.

In two large studies that used dietary questionnaires, reporting a high dietary intake of vitamin E was not associated with a lower risk of cardiovascular disease, but women and men who said they took vitamin E supplements regularly for two years or more had a lower incidence of coronary artery disease (Rimm EB, et al: *N Engl J Med* 1993; 328:1450; Stampfer MJ, et al: *N Engl J Med* 1993; 328:1444). Another questionnaire-based study in women found that reporting a high dietary intake of vitamin E was associated with a lower risk of death from coronary heart disease (Kushi LH, et al: *N Engl J Med* 1996; 334:1156). A double-blind intervention trial in patients with coronary atherosclerosis found that taking 400 or 800 IU of vitamin E daily for a median of 510 days (range 3 to 981) led to a statistically significant reduction in the incidence of nonfatal myocardial infarction. The incidence of cardiovascular death and all-cause mortality, however, was slightly higher in the patients who took vitamin E supplements than in those who took placebo (Stephens NG, et al: *Lancet* 1996; 347:781, 1996). A placebo-controlled intervention trial in Finnish smokers found little difference in cardiovascular risk but a lower incidence of prostate cancer and prostate-cancer mortality in those who took 50 IU of alpha-tocopherol daily (Virtamo J, et al: *Arch Intern Med,* 23 March 1998; 158:668; Heinonen OP, et al: *J Natl Cancer Inst* 1998; 90:440).

BETA CAROTENE AND VITAMIN A—Primary food sources for beta carotene are dark colored fruits and vegetables. Primary food sources for vitamin A are meats, fish oil, fish, and dairy products. Beta carotene and vitamin A are antioxidants, but may also have prooxidant effects *in vivo* (Omenn IGS, *Annu Rev Public Health* 1998; 19:73, 1998). Epidemiologic studies have found that higher levels of carotenoids in the diet and higher serum levels of beta carotene are associated with a lower incidence of cardiovascular disease and cancer, particularly lung cancer. Multivitamin preparations usually contain 1,000 to 10,000 IU (0.6 mg to 6 mg) of beta carotene. Beta carotene supplements usually contain 12 mg to 15 mg.

One large 12-year double-blind intervention study found that beta carotene supplements (50 mg every other day) had no effect on the incidence of cardiovascular disease or malignancy (Hennekens CH, et al: *N Engl J Med* 1996; 334:1145). A second placebo-controlled intervention trial in Finnish smokers found that 20 mg/day of beta carotene increased the incidence of lung cancer by 18%, which was statistically significant (The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group: *N Engl J Med* 1994; 330:1029). Another large double-blind intervention trial in smokers and asbestos-exposed workers, stopped early because no benefit was demonstrated, found that combined therapy with 30 mg of beta carotene and 25,000 IU of vitamin A daily was associated with an increase in the incidence of lung cancer, cardiovascular mortality, and total mortality (Omenn GS, et al: *N Engl J Med* 1996; 334:1150; Omenn GS, et al: *J Natl Cancer Inst* 1996; 88:1550).

VITAMIN D—Primary food sources of vitamin D are meat, fish and, in the U.S.A., fortified milk. Yogurt and other dairy products made with milk are generally not fortified with vitamin D. Many elderly people receive inadequate amounts of vitamin D because of low exposure to sunlight, decreased synthesis of vitamin D in the skin, and decreased absorption and activation of the vitamin. The latest U.S. recommendations for vitamin D intake, based on amounts that have retarded the rate of bone loss, are 200 IU/day for men and women 19 to 50 years old, 400 IU for men and women 51 to 70 years old, and 600 IU for men and women more than 70 years old. Elderly people who do not drink milk and do not expose themselves to sunlight will need to take supplements to achieve this level of vitamin D intake.

VITAMIN C—The main dietary sources of vitamin C in the U.S.A. are citrus fruits and tomatoes. Like vitamin E and beta carotene, vitamin C can have prooxidant as well as antioxidant effects (Herbert V: *Am J Clin Nutr* 1994; 60:157). One 8-oz glass of orange juice contains about 100 mg of vitamin C. Dietary levels of about 200 mg/day of vitamin C maintain maximal body pools of the vitamin

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(Levine M, et al: *Proc Natl Acad Sci* USA 1996; 93:3704). High intakes and serum concentrations of vitamin C have been associated with low incidences of senile cataract, cancer, and coronary artery disease, and higher high-density lipoprotein (HDL) cholesterol concentrations. No long-term intervention studies with vitamin C have been published. Short-term randomized trials have shown that taking vitamin C does not prevent upper respiratory infections.

High doses of vitamin C (more than 1 gram) are poorly absorbed and cause diarrhea, and could increase urinary oxalate excretion to a level that might increase the incidence of kidney stones. A controlled trial in 30 male volunteers given 500 mg daily of a vitamin C supplement found both increases and decreases in various markers of oxidative damage to the DNA of peripheral blood lymphocytes (Podmore ID, et al: *Nature* 9 April 1998; 392:559).

VITAMIN B_{12}—Food sources of vitamin B_{12} are meat, fish, and dairy products. Elderly people with atrophic gastritis, which affects 10% to 30% of Americans over the age of 60, cannot absorb vitamin B_{12} bound to food protein, but absorb crystalline vitamin B_{12} normally (Carmel R: *Am J Clin Nutr* 1997; 66:750). Elderly patients therefore should take vitamin B_{12} either in the form of B_{12}-fortified foods such as cereals or as a daily dietary supplement containing at least the Recommended Dietary Allowance (2.4 μg/day) of the vitamin.

FOLATE—The standard U.S. diet provides 50 to 500 μg of absorbable folate per day, mostly from meat and dark-green leafy vegetables, but the bioevailability of folate in mixed diets varies. Folic acid in supplements is about twice as bioavailable as folate in food (Oakley GP Jr: *N Engl J Med,* 9 April 1998; 338:1060). As of January 1998, all enriched cereal grains sold in the U.S.A. contain 140 μg of folic acid per 100 g of grain; estimates suggest that this fortification will increase folic acid intake by about 100 μg/day. Even this amount, however, may be inadequate for prevention of neural tube defects, which occur early in pregnancy, before most women know that they are pregnant (Daly S, et al: *Lancet* 1997; 350:1666). Supplementing the diet of women of childbearing age with 400 μg of folic acid per day has dramatically decreased the incidence of neural tube defects in their offspring (Czeizel AK, Dudas I: *N Engl J Med* 1992; 327:1832). Low intake of absorbable folates has also been associated with high serum concentrations of homocysteine and a higher incidence of cardiovascular disease and stroke (Boushey CJ, et al: *JAMA* 1995; 274:1049; Malinow MR, et al: *N Engl J Med,* 9 April 1998; 338:1009). High doses of folic acid can mask vitamin B_{12} deficiency, permitting progression of neurologic disease.

VITAMIN B_6 (Pyridoxine)—Vitamin B_6 is available in meat, whole-grain bread, and cereals, soybeans, and vegetables. Some retrospective studies have found an association between higher intakes of the vitamin, lower serum concentrations of homocysteine, and a lower risk of coronary heart disease (Rimm EB, et al: *JAMA* 1998; 279:359). Prospective studies are lacking, however, and the optimal dose and effectiveness of vitamin B_6 supplements remain to be determined (Omenn GS, et al: *Circulation* 1998; 97:421).

MULTIVITAMIN PREPARATIONS—Most multivitamin preparations contain amounts of vitamins and minerals that are safe. One randomized trial in 96 elderly patients in Canada found that those who took such preparations for 12 months showed signs of better immune function and had fewer sick days (Chandra RK: *Lancet* 1992; 340:1124). A much larger, but retrospective, study in U.S. adults found that taking vitamin supplements was not associated with lower morbidity and mortality rates (Kim I, et al: *Am J Public Health* 1993; 83:546).

DIET—Many substances found in foods may affect the occurrence of heart disease and malignancy, but they may not all be vitamins. Supplementing the diet with vitamins may not be an adequate substitute for the beneficial effects of a diet rich in fruit and vegetables.

CONCLUSION—Supplements are necessary to assure adequate intake of folic acid in young women and possibly of vitamins D and B_{12} in the elderly. The benefits of taking high doses of vitamin E remain to be established. There is no convincing evidence that taking supplements of vitamin C prevents any disease. No one should take beta carotene supplements. A balanced diet may be more beneficial and safer than taking vitamin supplements.

50 Years Ago

From *The Connecticut State Medical Journal*

September 1948

Actuarial Society Analyses Surgical Benefit Claims

Boys incur 15 per cent more surgical operations than girls, with 60 per cent of all children's operations being tonsillectomies and 20 per cent appendectomies or fractures, according to an analysis of 100,000 surgical benefit claims of all ages made by a committee of the Actuarial Society of America and presented at the annual meeting of the Society in New York.

This was one of a long list of findings from the study which covered group surgical insurance claims reported by companies doing 70 per cent of this type of insurance and covering a period of eight months of last year.

Group surgical insurance, first written in 1938, has become an important segment of the insurance business, covering 10,000,000 persons, the report stated. This insurance, added to protection on an additional 10,000,000 covered by Blue Cross, individual contracts or other plans, gives a total of over 20,000,000 persons now protected by surgical benefit insurance.

Eight types of operations were found to account for the greater part of all surgical benefit claims: tonsillectomy, appendectomy, benign tumor or cyst, hemorrhoidectomy, fracture, hysterectomy, herniotomy and dilation or curettage. These accounted for 60 per cent of all claims, 57 per cent of the male cases and 67 per cent of the female cases.

Multiple operations take place in a large number of cases, taking advantage of the urgency of the major cause. In 17 per cent of all cases, more than one operation was performed under the one procedure; in the case of claims for wives, 31 per cent were multiple, for female employees, 24 per cent, for male employees 15 per cent and for children 5 per cent. In gynecologic surgery, a maximum of 51 per cent was shown. On the average, multiple operation claims were for amounts almost double those for single operations.

More complicated surgery was incurred at ages over 50 in the case of men. For women, the operations were generally more serious than for men at all ages, but the severity changed little with age, except for a slight peak in late child-bearing or post child-bearing years.

Not all surgery is performed in hospitals, the report shows, though most of it is. Men show a higher out-of-hospital surgery incidence than women. In the case of men, 23 per cent of the operations were performed out of hospitals, for children, 16 per cent and for women 11 per cent. The average amount paid for out-of-hospital claims was less than one-third that for hospital surgery.

Taking appendectomy as an example, it was found that 30 per cent of the doctors charged not over $100; 50 per cent not over $125; 80 per cent not over $150; and 90 per cent not over $165.

The analysis was said by the committee to indicate that charges were usually higher for male employees than for women, reflecting the general practice of suiting fees to the ability to pay.

Analysis of surgical fees in the cases covered showed that charges were highest on the west coast, with California showing the highest cost of any state. In California the charges were 39 per cent greater than the U. S. average in nonobstetrical cases and 61 per cent over average in obstetrical; in the middle Atlantic states, next highest, the charges were 3 per cent and 5 per cent higher than average, respectively. The south Atlantic states showed the lowest cost, 12 per cent and 9 per cent, respectively, below average.

The average surgical claim for male employees was $48, for female employees $63, for wives $71. for male children $34 and for female children $37.

First International Poliomyelitis Conference

The United States acted as host to medical leaders from about 60 foreign governments during the 6-day conference held in New York City in July. In addition to these

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Reprinted from the *Connecticut State Medical Journal*, September 1948.

official delegates there were present representatives of invited universities, societies and scientific and philanthropic organizations interested in research and treatments of virus diseases as well as physicians and other scientific and professional persons qualified by recognized standards.

The delegates were welcomed by D. Basil O'Connor, president of the National Foundation. Foreign delegates were introduced by Morris Fishbein, editor of the *Journal of the American Medical Association.*

The session included panel discussions and presentation of medical and scientific papers on poliomyelitis. There were demonstrations of scientific apparatus used in research and treatment of the disease, medical and scientific exhibits, receptions, entertainment and excursions.

John R. Paul, professor of preventive medicine at Yale University School of Medicine, reported the possibility that the properties of poliomyelitis virus may change in time. Dr. Paul declared that in carrying the Lansing (human) strain of polio virus through mice, it may become "contaminated" with a polio-like virus which occurs spontaneously in mice. At least two neurotropic viruses have been found in mice, he noted, but these do not "take" in monkeys and presumably are incapable of infecting humans. From this, Dr. Paul believes, indications can be gained on the evolution of polio virus.

Dr. Paul outlined 5 general characteristics of the polio virus: preference for gray matter of the central nervous system; it is recoverable from the intestinal tract of the infected host; it is one of the smallest known; it attacks man alone in nature and the primates and three types of rodents experimentally; and it resists ether, a characteristic which enables the researcher to rid virus containing substances of other contaminants so that more complete studies can be accomplished.

Considerable discussion arose over the cost of the Sister Kenny treatment. Professor Herbert J. Seddon of Oxford University made the statement that the Kenny treatment was several times more expensive than the so-called orthodox treatment. Sister Kenny challenged this statement. Dr. Fishbein attempted to reconcile both factions by saying that it was not possible to compare the expenses of different treatments, because their variations by physicians and in various institutions were too great and because there was no standard by which to measure them.

Physical activity after the onset of the disease was felt to contribute importantly to the severity of the paralysis. William T. Green, professor of orthopedic surgery at Harvard Medical School, said too much emphasis has been placed on minutiae in the management of the after effects of polio rather than on fundamental considerations. "No treatment," said Dr. Green, "is good a priori; it may be good or bad depending upon the particular patient at a particular time. Means must be subordinated to the end."

A message was read from President Truman. At the dinner meeting Frank R. Ober, professor of orthopedic surgery at Harvard Medical School, and R. L. Sensenich, president of the American Medical Association, were among the speakers. Several physicians from Connecticut attended the conference.

COMPAC Revisited and a New Editor for *Connecticut Medicine*

Just as I was wondering if anyone reads what I write on this page, I was given a copy of an article in *The Journal Inquirer* entitled "State medical society sets $700,000 political fund goal." Apparently the reporter, Don Michak, had read my President's Page last month on the topic of contributing to COMPAC.

Mr. Michak quoted me accurately and in context, something not all reporters are so careful about. He even observed, "While individual doctors and their spouses often have been active in campaign fund raising, organized medicine, with the exception of the American Medical Association, has not played a major role in financing Connecticut political candidates."

Perhaps unintentionally, the article suggested a whiff of something a bit unsavory in physicians setting a goal of hundreds of thousands of dollars to influence state-wide elections. How ironic it is then that the level of participation in COMPAC by Connecticut physicians is pathetic.

Is anybody else, besides Mr. Michak, listening out there? Please don't put it off any longer. Write a personal check for $100.00 to COMPAC, today.

I am pleased to announce that, following the resignation of longtime editor Robert U. Massey, M.D., and the interviewing of several candidates, a new editor has been appointed to *Connecticut Medicine*. H. David Crombie, M.D. of West Hartford will assume his duties, following a transition period, around the first of the year.

Dr. Crombie is a general surgeon and is currently the Associate Director of the Department of Surgery and Chief of General Surgery at Hartford Hospital. He is also an Associate Professor of General Surgery at the University of Connecticut School of Medicine. Following medical school at Tufts, residency training at Hartford Hospital, and two years in the U.S. Navy, he joined the Hartford Hospital staff in 1969.

In addition to his practice, he has maintained a strong interest in surgical education and in the humanities in medicine, particularly ethics, philosophy, and the history of medicine. He had a long association with the Hartford Hospital *Bulletin* culminating with his assuming the editorship until it was phased out by the Hospital. He is the Librarian of the Hartford Medical Society. In 1992, he was the co-editor with Dr. Massey in the production of a bicentennial booklet on the Hartford County Medical Association (1792-1992) which was an award winner in this genre at the national level.

Dr. Crombie will be looking forward to building upon Dr. Massey's strong foundation at the journal. He has also expressed an interest in hearing suggestions from the readers on how they would like to see it improved. I encourage you to write to him with any ideas you may have. I would also encourage my colleagues around the state to consider writing for our journal. We always have a need for scientific articles as well as opinion pieces. Let Dr. Crombie hear from you.

Please join me in welcoming Dr. Crombie to his new position and in thanking Dr. Massey for a job well done.

Craig W. Czarsty, M.D.
President

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A Question of Virtue

ROBERT U. MASSEY, M.D.

> As to diseases, make a habit of two things—to help, or at least to do no harm,
>
> Hippocrates, *Epidemics* I, xi (Jones)

ONCE or twice this past year I have read that some plaintiff's lawyer had reminded a physician that he had sworn "to do no harm" in the oath he took when he received his M.D. degree. The Oath in whatever form, either the Hippocratic Oath as it appears in Francis Adams's translation or the watered-down WHO version, contains no such admonition.

The closest it comes is "Into whatever houses I enter, I will go into them for the benefit of the sick," and perhaps more so in the, now problematic, lines: "I will give no deadly medicine to anyone if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion," In other words, always help, never harm.

"[T]o help, or at least to do no harm" is buried in the "Epidemics," and is close to the medieval Latin, "primum non nocere," in the first place do no harm. Pellegrino refers to this as a "Hippocratic principle," and a "Hippocratic ideal," and reads into it an admonition above all to be competent.[1] Of the four principles of biomedical ethics which all medical students now memorize—autonomy, beneficence, nonmaleficence, and justice—it is, of course, the third. It stands out because among a group of three "thou shalts" it is the only "thou shalt not."

Engelhardt warns that "the obligation to be nonmalevolent is stronger than the obligation to be beneficent." He suggests that the intended good may, in fact, be a harm, and that sometimes the provision of a good may "be in some sense wrong."[2]

Judgment about these matters is rarely easy in a multicultural, diverse society, in which only a few believe ethical principles are absolute, resting either upon religious conviction or a Platonic reality of the good, the true, and the beautiful. "Just do the right thing," but what is right when most consider eithics relative, a matter of how one feels at the moment, or whom one talked to last? Take the matter up with a committee? Ask a lawyer?

Pellegrino and Thomasma have suggested that ethics, medical ethics in particular, should be virtue-based rather than principle-based.[3] A revival of virtue ethics may be the road back to consensus in morality, but, of course, our political masters and academic leaders will immediately ask, "Whose virtues are we talking about?"

Aristotle named four: prudence, temperance, fortitude, and justice; St. Paul added three more, faith, hope, and love, with love being the greatest of all. Everyone can make up his own list so long as it is in addition to Aristotle's! Pellegrino and Thomasma list these: fidelity to trust, compassion, phronesis (competence, "medicine's indispensible virtue"), justice, fortitude, temperance, integrity, and self-effacement.[3] And Osler added aequanimitas:

> In the first place, in the physician or surgeon no quality takes rank with imperturbabilty, and I propose ... to direct your attention to this essential bodily virtue.... Imperturbability means coolness and presence of mind under all circumstances, calmness amid storm, clearness of judgment in moments of grave peril, immobility, impassiveness, or, to use an old and expressive word, *phlegm.* It is the quality which is most appreciated by the laity though often misunderstood by them; and the physician who has the misfortune to be without it, who betrays indecision and worry, and who shows that he is flustered and flurried in ordinary emergencies, loses rapidly the confidence of his patients.[4]

Pellegrino interpreted "do no harm" as competence, but added that today it must be supplemented by "Do all things essential to optimal solution of the patient's problem."[1] But harm is done in other ways, too: by being discourteous, by failing to make friends with the patient, by cheating her in spending too little time, by taking an inadequate history and doing a "focussed" examination, missing the

---

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

melanoma or the aortic diastolic murmur or the bump on his prostate or the lump in her breast, by failing to write a timely letter to the referring physician, by not visiting hospital patients on Sunday morning, by withholding empathy, by failure of love.

And what about those outfits with the Orwellian name: Health Maintenance Organizations? Should they not be held to ethical behavior, whether virtue-based or principle-based? If not, should they not then get out of the way of medical practice, go find some other way to make a buck?

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2. Engelhardt HT Jr: *The Foundations of Bioethics.* 2nd ed. New York, N.Y: Oxford University Press; 1996:110.
3. Pellegrino ED, Thomasma DC: *The Virtues in Medical Practice.* New York, N.Y: Oxford University Press; 1993.
4. Osler W: *Aequanimitas.* Philadelphia, Penn.: The Blakistone Press; 1945:3–4.

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

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This Month's Reading in Review

TIMOTHY B. NORBECK

"The AMA has long believed an antitrust exemption for self-employed physicians is needed to level the playing field. Antitrust laws have been interpreted to allow health plans such a high degree of leverage that an appropriate balance of interests no longer exists in the market for health care delivery and finance. As a result, the power of health plans to determine the kind of health care that patients receive is virtually unchecked. While health plans have achieved many significant accomplishments, it is not healthy for any interest group to have virtually unlimited power over an issue as significant and sensitive as the kind of treatment needed by an individual with an illness or injury."

29 July testimony of AMA Trustee Donald J. Palmisano, M.D., J.D., before the U.S. House Judiciary Committee in support of The Quality Health-Care Coalition Act of 1998, H.R. 4277. The legislation would modify the antitrust laws to allow individual physicians to collectively bargain with health plans and to be more effective patient care advocates.

NOTE: CSMS member Michael P. Connair, M.D., also testified at the hearing in support of H.R. 4277, representing AFSCME (American Federation of State, County and Municipal Employees, AFL-CIO).

"Turning decisions about health-care coverage over to employees is not a criticism of employers' efforts. Many do a good job of providing their employees with quality health care options. Still, it makes much more sense to put decisions about health care directly in the hands of those receiving the services."

AMA President Nancy W. Dickey, M.D., in promoting an AMA proposal to have employers provide a defined contribution for each employee's coverage.
Dallas Morning News (2 August 1998)

Let's Eat Out: Don't use your cutting board – use your toilet seat instead. After testing various household surfaces in 15 homes for bacteria, researchers from the University of Arizona told *New Scientist* magazine that toilet seats were much more hygienic than most kitchen surfaces.

Internet (22 July 1998)

"The most imposing fact about the market-medicine HMO system, now spreading at enormous speed across the land, is that nobody voted for it, nobody was consulted about it, and nobody elected it. Yet it holds the power of life and death over patients, and arbitrates the professional role of doctors and nurses, and is accountable only to itself and to unforeseeable fluctuations in the stock market."

Vanity Fair (August 1998)

"Insurance companies dislike plans that allow the patient to choose the doctor on his own. And for the health insurance consumers who want them, these plans are prohibitively expensive. We can remedy this problem with a simple amendment to the patients' bill of rights. Allow patients to go to any doctor that they choose, as long as the doctor accepts the fee schedule of the plan. And we could allow patients to go to doctors who won't accept the plan's fee schedule as long as the doctor accepts the fee schedule as partial payment. This would allow the greatest access to health care of any proposal out there."

From a letter to the *New York Times*
(27 July 1998)

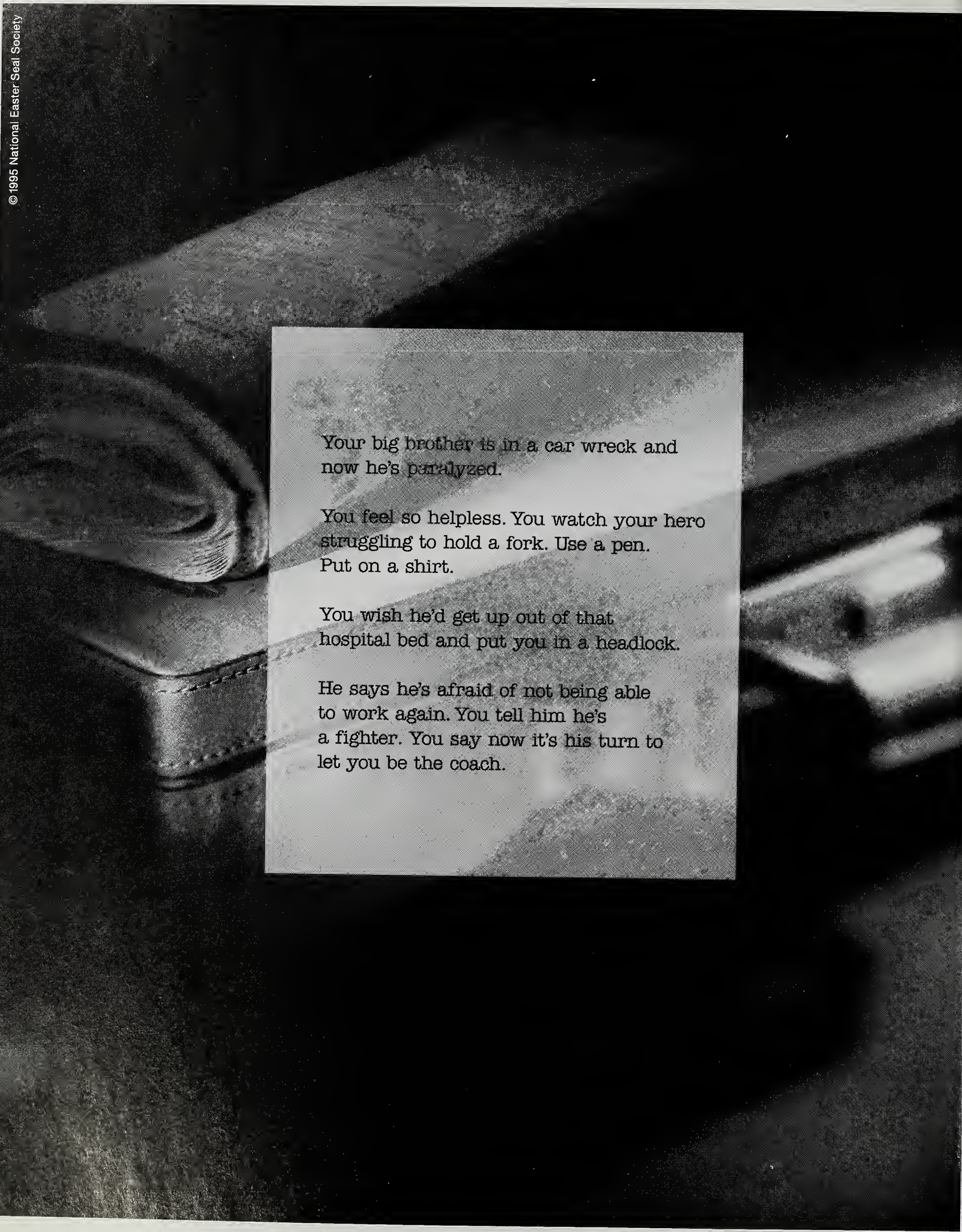
"All these politicians share a desire to help consumers, but isn't it amazing that they waited to act until an election campaign? ... This is one issue that should transcend partisanship. Consumers may be voters but they don't want to see health care become a campaign volleyball."

An editorial in the *Baltimore Sun*, discussing politics and the patients' rights issue.
(26 July 1998)

"To be sure, litigation is a costly and unpredictable way to protect consumers' rights. But managed care companies are making more and more medical decisions, and it's difficult to see why they should be shielded from malpractice suits when doctors are not. Indeed, the threat of litigation might be the best incentive for HMOs to establish effective and fair appeals procedures for their patients."

An editorial in the *Minneapolis Star Tribune*, supporting patients' right to sue HMOs.
(26 July 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.



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Your big brother is in a car wreck and now he's paralyzed.

You feel so helpless. You watch your hero struggling to hold a fork. Use a pen. Put on a shirt.

You wish he'd get up out of that hospital bed and put you in a headlock.

He says he's afraid of not being able to work again. You tell him he's a fighter. You say now it's his turn to let you be the coach.

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CPRO Focus Is Now on Quality Improvement Through Collaboration

It has been almost four years since the quality improvement methodology of peer review organizations changed dramatically, but many practicing physicians are still not aware of the new approach. In fact, we now refer to ourselves as Quality Improvement Organizations (QIOs) rather than peer review organizations (PROs). CPRO's new vision, "Better Health Through Better Health Care Information," very succinctly says it all.

CPRO no longer performs massive amounts of individual case review. Since 1993, our focus has been on collaborating with heath care providers and community organizations in projects to improve the care received by Medicare beneficiaries through what Medicare refers to as the Health Care Quality Improvement Program (HCQIP). These projects have demonstrated the value of working together to share lessons learned and analyzing information for selected conditions to identify opportunities for improvement. This effort is led by several physicians who serve as clinical coordinators, and our staff of project coordinators, epidemiologists, and data analysts.

Although the early projects undertaken by CPRO and its partners focused on health-care provided in the state's acute care hospitals, HCQIP is now expanding beyond the hospital walls to keep up with the concept of integrated delivery systems. CPRO is now conducting quality improvement projects in settings such as physician offices, long-term care, and home care. For example, the M.O.R.E. (Mammography Optimum Referral Effort) project is a good example of this expansion. It involved nearly 40 individual physicians in private practice recruited by our clinical coordinator, Jeanette A. Preston, M.D. These physicians are from three geographic areas (Bridgeport, Windham, and the Lower Naugatuck Valley).

These areas were selected because Medicare data indicated that mammography utilization was lower there than in other parts of the state. The participating physicians agreed to counsel female Medicare patients who came to their offices—for any reason—to get a mammogram. Medicare claims data are being used to track the success of this effort and we are very enthusiastic about the preliminary results which are showing a marked increase in mammography utilization.

Physicians in private practice are also being recruited to participate in a regional diabetes project led by clinical coordinators Martha Radford, M.D. and Gary Cohen, M.D. The project will promote increased adherence to accepted processes of care for diabetics.

Two years ago, CPRO was approached by the *Connecticut Thoracic Society* to collaborate on a project to develop an evidence-based clinical pathway for the treatment of community-acquired pneumonia. Thomas Meehan, M.D., M.P.H., CPRO's Principal Clinical Coordinator, and Jonathan Fine, M.D., of the *Connecticut Thoracic Society* and Norwalk Hospital, are spearheading this effort. Twenty-six hospitals actively participated in the planning, development, and implementation of this project which focuses on the diagnosis and treatment of patients hospitalized with pneumonia. Interest in this project has been expressed from medical professionals in states as far away as California and North Dakota.

The Cooperative Cardiovascular Project (CCP), a national effort to improve the care of AMI patients, was piloted in four states, including Connecticut. Clinical coordinators Harlan Krumholz, M.D. and Martha Radford, M.D. continue to play key roles in this project on both a state and national level. All acute care hospitals in the state are involved in this activity.

Managed-care organizations are also among the new partners working with CPRO toward the common goal of improving health care. CPRO is currently working with one of Connecticut's Medicare managed-care plans to profile preventive care services and determine barriers preventing increased utilization. In addition, CPRO is working with the plans contracting with Medicaid to develop three projects over the next two years.

Although CPRO's contract with Medicare is its largest, it is by no means the only one. In August 1996, CPRO was named a subcontractor for Rhode Island Quality Partners, the new QIO in that state. Under this contract CPRO provides a wide range of services including project management and data analysis. Since 1989, CPRO has had a contract with the State of Connecticut to conduct review of patients with Medicaid insurance. Since 1 July 1996, CPRO also has been performing review of Medicaid fee-for-service clients in the State of Rhode Island.

In addition, CPRO was awarded a contract in 1996 to serve as the external quality review organization for the Connecticut Medicaid Managed Care Program. This contract features three components: an operations audit of the 11 participating health plans; development of a data base to facilitate quality improvement activities, future planning, and program design; and quality improvement studies in areas such as pediatric asthma, diabetes, high-risk pregnancy, dental care, and behavioral health.

CPRO physicians and also staff are actively involved in statewide coalitions promoting mammography, influenza and pneumococcal disease immunizations, as well as beneficiary outreach and education. These partnerships are further examples of our new approach, which emphasizes improving the quality of care by improving the system which delivers that care.

"I have been involved with peer review and quality improvement at CPRO for more than four years," said Dr. Cohen, Medical Director and Associate Clinical Coordinator. "During this time I have seen the focus of PRO quality improvement change to what is clearly more collaborative work with practicing physicians, in order to help achieve our common goal, improvement in patient care. Our work is currently focused on profiling processes and outcomes of care for common conditions. Our goal is to positively impact the way care is delivered."

Other CPRO quality improvement projects include: peptic ulcer disease, stroke prevention in patients with atrial fibrillation, congestive heart failure, and many more. Future articles in *Connecticut Medicine* will feature highlights on some of these individual projects as well general health care quality improvement issues.

Groups which have recently partnered with CPRO include:

Connecticut Chapters of Medical Specialty Societies: American College of Cardiology, American Radiology Society, American Thoracic Society.

Private and Professional Organizations: Albert B. Sabin Vaccine Foundation, American Cancer Society, American Heart Association, American Lung Association of Connecticut, Connecticut Association of Directors of Health, Connecticut Association of Not-for-profit Providers for the Aging, Connecticut Association for Home Care, Connecticut Health Information Management Association, Connecticut Hospital Association, Connecticut Nurses Association, Connecticut State Medical Society, Elderly Health Screening Service, Infectious Disease Society of America, Rhode Island Medical Society, Sickness Prevention Achieved through Regional Collaboration (SPARC), St. Francis Senior Health and Wellness Center, and the VHA of Southern New England.

Academic Medical Centers: Beth Israel Hospital (Boston), Cedars-Sinai Health System, Los Angeles, CA, Harvard Medical School (Boston), University of Connecticut School of Medicine and Graduate School, the University of Pittsburgh School of Medicine—Pneumonia PORT, and Yale University School of Medicine and Public Health "It has been a pleasure working with the clinicians and administrative staff of Connecticut health-care institutions as we strive to achieve our vision, 'Better Health Through Better Health Care Information,'" said Thomas P. Meehan, M.D., M.P.H. Dr. Meehan is CPRO's Principal Clinical Coordinator.

Physicians and other health-care providers interested in collaborating with CPRO in the future invited to contact Dr. Meehan at (860) 632-6330.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

Thanks

Letter to the Editor: Thanks so much for your very kind comment in the July issue of *Connecticut Medicine* regarding the honorary degree event at Connecticut College.

This is all very nice. What really troubles me is, however, I never did anything in my professional life, whether it be in the office, hospital, or community at large that I didn't think a "doctor was supposed to do" ... I guess there were many advantages in my younger years to be mentored by such leaders as Ed Wakeman, and later his son Maurice, Grover Powers, Edith Jackson, Milton Senn, to mention only a few who come to mind.

It seems to me that it is imperative that physicians realize that they are members of the wider community and should take the lead in leadership, in whatever form it fits their ideas and ideals.

Morris A. Wessel, M.D.
New Haven

Anonymous Poem "My Daddy, M.D."

Letter to the Editor: An aunt of mine recently sent me the following poem which is framed on her doctor's office wall! (In South Carolina.) I had never seen it and thought you might like it for the *Journal*. The source is anonymous.

Allen R. Koenig, M.D.
Cos Cob

My Daddy, M.D.

Whenever Daddy signs his name
He always writes M.D.
So people all will know
That he belongs to me.

For M.D. means My Daddy
Or something just the same
And that is why he always puts
These letters in his name.

Some letters in his name are small
But these are not you see
He always makes them big like that
Because he's proud of me.

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Neil J. Grey, M.D.
Medical Director

Michele R. Norbeck
Director

PAIN MANAGEMENT STRATEGIES

FOR THE PRIMARY CARE SPECIALIST

Friday, November 20, 1998

The course is directed to primary care specialists who have an interest in the overall evaluation of the patient with pain and in the various modalities of pain management. This includes general practitioners, family practice physicians, internists, psychiatrists, neurologists, and all health professionals whose practice involves the care of patients suffering from acute or chronic pain.

The program will present a primer of the latest developments in the pathophysiology, diagnoses and treatments of pain. Each talk will focus on specific topics directly relevant to the practical problems that a primary care specialist may encounter when confronted with a pain patient. It will summarize the main solutions available to provide the best "state of the art" care to such a patient. Pain specialists from eight different specialty backgrounds will contribute to this meeting and will bring their unique experiences and points of view. This diversity will make this program a truly comprehensive review course. In addition, two sessions will be spent on clinical case presentations which will allow interaction and discussion of "real pain problems" with the participants.

The goal of the course is to familiarize the participants with the latest diagnostic and therapeutic tools available to the primary care specialist in order to deal with the large variety of pain problems. It will also help to define the relative role of the primary care specialist and of other specialists in the overall management of pain patients and their interaction. Finally, the participants will be given enough time to ask questions of the faculty.

At the conclusion of the course, the participants should be aware of all current basic advances in the field of pain medicine.

Course Director: Michel Y. Dubois, M.D. **Course Co-Director:** Gerard Varlotta, D.O.

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From the Executive Director's Office

CALL

SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1998 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway, Meriden. The meeting will commence at 12:30 P.M. on Thursday, 19 November and will continue until all business has been concluded.

Craig W. Czarsty, M.D., President
Howard J. Wetstone, M.D., Speaker of the House
Brian Van Linda, M.D., Secretary

11:30	Registration of Delegates Luncheon
12:30	Call to Order Business of the House Guest Speaker: Percy Wootton, M.D., Immediate Past President, AMA

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

b. *Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of the Society at any time and shall be considered as regular business.*

d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

* *

All past presidents of the Society and Alternate Delegates are ex-officio members of the House of Delegates without the privilege of voting.

* *

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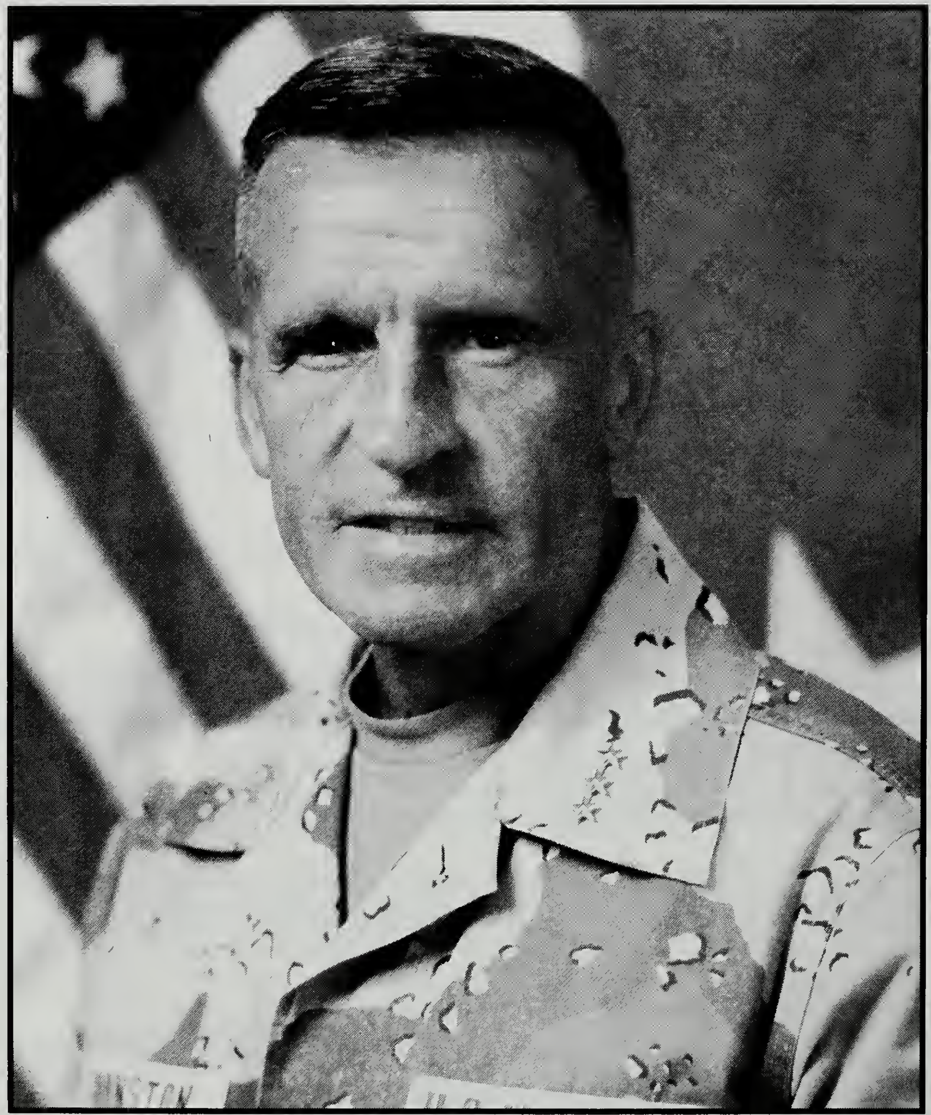

Lt. Gen. Robert Johnston, USMC Ret., Chief of Staff of Operation Desert Storm, is fighting mad. He's joined MDA's battle to save lives. The general knows the enemy – life-threatening diseases that attack and eventually kill children and adults. Join the general in this great battle by volunteering to help MDA. Call your local MDA office or **1-800-FIGHTMD**. You'll help win the war against neuromuscular disease.

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IN MEMORIAM

ATWOOD, ALBERT S., Yale University School of Medicine, 1945. Dr. Atwood was an orthopaedic surgeon at the Charlotte Hungerford Hospital for 25 years. He served as a consultant for the Newington Hospital for Children. Dr. Atwood was named the first chairman of the department of rehabilitation at Lawrence and Memorial Hospital in 1977. He served as the medical director of the South Eastern Connecticut Easter Seal Chapter. After his retirement in 1987, Dr. Atwood worked as a surveyor for the Joint Commission for the Accreditation of Hospitals. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society where he served on the Committee on Legislation during the 1970s, and the American Medical Association. Dr. Atwood died 8 August 1998 at the age of 77.

COVEY, SUSAN S., State University of New York College of Medicine, 1970. Dr. Covey was a radiation oncologist and member of the clinical faculty at Yale. She was a member of the Fairfield County Medical Association and the Connecticut State Medical Society. Dr. Covey died 31 July 1998 at the age of 55.

DEAN, MICHAEL A., Tufts University School of Medicine, 1943. Dr. Dean, a surgeon, served as a clinical professor of surgery at Yale University School of Medicine. He was a member of the courtesy staff of both Park City and Bridgeport Hospitals. Dr. Dean served as chief of general surgery and president of the staff at St. Vincent's Medical Center, retiring in 1986. He was a member of the Fairfield County Medical Association where he served as an officer and as a delegate to the Connecticut State Medical Society, the Connecticut State Medical Society where he served on many committees and as an alternate delegate to the American Medical Association, and the American Medical Association. Dr. Dean died 26 July 1998 at the age of 81.

DUGAS, JOSEPH A., Loyola University Stritch School of Medicine, 1938. Dr. Dugas, a family practitioner, practiced medicine for 53 years and was in private practice for 46 years, retiring in 1991. Dr. Dugas was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Dugas died 28 July 1998 at the age of 84.

FENNEY, PHILIP W., Tufts University School of Medicine, 1931. Dr. Fenney was chief surgeon at the Newington Veterans Home and Hospital for 25 years, retiring in 1983. He served as the medical director of social welfare with the State Welfare Department from 1946 to 1947. Dr. Fenney was a member of the Hartford County Medical Assoc. and the Connecticut State Medical Society. Dr. Fenney died 16 August 1998 at the age of 91.

HOLDEN, WESLEY W., New York University School of Medicine, 1947. Dr. Holden practiced obstetrics and gynecology in Bristol from 1953 until his retirement in 1996. He served as chief of staff of the department of obstetrics and gynecology at Bristol Hospital several times during his career. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Holden died 13 August 1998 at the age of 75.

LOVETERE, ANGELO A., George Washington University School of Medicine, 1925. Prior to his retirement in 1952, Dr. Lovetere specialized in allergies and practiced in the New Britain area. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Lovetere died during the week of 8 August 1998 at the age of 89.

PARSHLEY, PHILIP F., University of Pennsylvania School of Medicine, 1927. Dr. Parshley practiced medicine in West Hartford for 40 years and was on the teaching staff of Hartford Hospital. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Parshley died 6 August 1998 at the age of 96.

ROCCO, ANTHONY R., Facolta di Medicina e Chiurgia dell'Universita di Napoli, Italy, 1957. Dr. Rocco maintained a private pediatric practice in West Haven for 30 years. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Rocco died 28 July 1998 at the age of 72.

SHOUKIMAS, JOHN, Harvard Medical School, 1942. Dr. Shoukimas was a former chief of surgery at St. Francis Hospital and Medical Center. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Shoukimas died 19 August 1998 at the age of 81.

VEEDER, RAYMOND, Medical School Kings College University of Durham, England, 1952. Dr. Veeder practiced psychiatry at the Institute of Living for 30 years. During that time, he served as supervisor of residents, the first director of the day treatment center, clinical director, director of admission services, and senior clinical director. He was a nationally recognized volunteer at the Community Health Services, a clinic in the North End of Hartford. He served as a consultant to the Hartford Police Department as well as police departments in 29 area towns and to the Connecticut State Police. Dr. Veeder was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Veeder died 10 August 1998 at the age of 79.

WHITCOMB, BENJAMIN B. JR., McGill University Faculty of Medicine, Montreal, 1935. Dr. Whitcomb was a member of the neurosurgical staff at Hartford Hospital from 1946 to 1973 and was a former director of neurosurgery there. He was associated with Mount Sinai Hospital and served as a consultant to the Institute of Living and the Veterans Administration Hospital in Newington. In 1949, Dr. Whitcomb was instrumental in developing the Hartford Hospital–Yale University neurosurgery residency program. He was a clinical professor of medicine at Yale University School of Medicine and the University of Connecticut School of Medicine. Active in numerous local, state, and national neurological societies, Dr. Whitcomb was a member of the Hartford County Medical Association, and the Connecticut State Medical Society where he served on the Cancer Coordinating Committee during the 1970s, and on the Technical Medical Advisory Committee to Crippled Children

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***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

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Available July 1999. Licensed in Connecticut. Passed National Boards, American Board certified. M.D. at Dartmouth Medical School. Internship and residency at John Hopkins Bayview Medical Center. Looking to join a group practice in a small to medium sized community. Please respond to: John A. TenBrook, Jr., M.D., 29 Lincoln Woods Way #2C, Perry Hall, MD 21128; telephone (410) 931-3289.

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LINSCO Financial Services
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Greg Pepe, CEO
M.D. Advantage
Positioning Your Practice
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The Consumer Affairs Division of the Department of Insurance receives, reviews, and responds to complaints and inquiries from state residents concerning insurance related problems. The staff examines each complaint to determine whether statutory requirements and contractual obligations within the commissioner's jurisdiction have been fulfilled. The Consumer Affairs Division coordinates the resources available within the Department to address consumer complaints.

In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

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Address: ______________________________________

Phone where the Department can contact you: (_____) ____________________

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Policy Number: ______________________________

Name of Policyholder: ______________________________

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Name of Patient: ______________________________

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You Are Invited to an Educational Program on Alzheimer's Disease: Innovations, Treatments & Caregiving Methods

Wednesday, October 28, 1998
8:30 a.m. – 11:00 a.m.
Radisson Hotel, Cromwell, CT *(Conveniently located off I-91; Exit 21)*

***Sponsored by*:**
Alzheimer's Association of Northern Connecticut
Bayer Corporation
Commission on Aging – State of Connecticut
Connecticut State Medical Society

"Physicians and Caregivers – Partners in Progress"

8:30 - 9:45 a.m. Keynote Session and Breakfast

Medical Advances and Innovations
Alan Siegal, M.D., Past President, American Association for Geriatric Psychiatry

Connecticut's Legal Advocacy System
Cynthia Matthews, Executive Director, State of CT Commission on Aging

Respite Care Relief, Safe Return Program and Support Groups
Ms. Kathleen Teso, Executive Director, Alzheimer's Association Northern CT Chapter

Breakout Sessions

(10 - 11 a.m.)

Physician Session	Caregiver Session
"Treatment and Management of the Alzheimer's Patient and Coding Issues"	**"How to Care for the One You Love and Yourself "** - A Roundtable Discussion
Speaker *Alan Siegal, M.D., Past President* *American Association for Geriatric Psychiatry*	*Speakers* *Ms. Kathleen Teso, Executive Director* *Alzheimer's Association of Northern CT* *Ms. Pamela Atwood, Dir. of Education and Training* *Alzheimer's Association of Northern CT* *Mr. Richard Amill, Caregiver* *Alzheimer's Association, Fairfield County Chapter* *Ms. Delores Caffery, Caregiver* *Alzheimer's Association, Southern CT Chapter*

Registration Information

To register, contact Kate at the Alzheimer's Association Northern Connecticut Chapter, 1-800-356-5502. RSVP by October 20, 1998.

There is no registration fee, however, a voluntary, tax-deductible donation to Alzheimer's Association Northern Connecticut Chapter, would be greatly appreciated (790 Maple Avenue, Hartford, CT 06114).

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Target Audience
Health Care professionals: physicians, registered nurses, physician assistants, nurse practitioners, certified nurse practitioners

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- **The Critical Role of Physicians in Accountable Health Care Organizations**
- **1999 CPT and ICD-9-CM Coding Changes**
- **Improving Patient Care at the End of Life**
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* The American Medical Association is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

** The AMA designates this educational activity for a maximum of 4.5 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

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Connecticut State Medical Society

Semi-annual Meeting—House of Delegates

18 November 1998

11:30 a.m.—Registration and Luncheon
12:30 p.m.—Call to Order

Ramada Inn, 275 Research Parkway, Meriden

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 OCTOBER 1998 NUMBER 10

scientific:

Linda Lee, Barry Wu, Helena Brett-Smith, and Paul Fiedler 579 **Human Immunodeficiency Virus–related Progressive Multifocal Leukoencephalopathy with a CD4$^+$ of 444 per mm^3: A Case Report**
David P. Neumann and Hilario Martinez 583 **Intracranial Subependymoma**
Nagarajan Ramakrishnan and Lewis P. Parker 587 **Thrombotic Thrombocytopenic Purpura Following Influenza Vaccination—A Brief Case Report**
Epitomes of Progress
Daniel A. Nachtsheim 589 **Important Advances in Clinical Medicine—Urology**
Morbidity and Mortality Weekly Report
595 **Changes in Mortality From Heart Failure—United States, 1980–1995**

special articles:

Sundaram V. Ramanan 601 **James Bryan Herrick: A Man of Intellectual Muscle**
Robert S. Walzer 605 **Principles of Cooperation in Medical-Legal Matters**

commentaries:

Richard J. Mangi 615 **The Primary Care Physician and Managed-care**
Stephen R. Katz 619 **The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America**

guest editorial:

Richard Melchreit 621 **Widespread HIV Antibody Testing of Pregnant Women—How Accurate?**

departments:

Fifty Years Ago
623 **The Candidates Speak**
The President's Page
Craig W. Czarsty 625 **Rising Health-care Costs and Physician Unity**
Reflections on Medicine
Robert U. Massey 627 **Signs of the Times?**
Medical News Capsules
Timothy B. Norbeck 629 **This Month's Reading in Review**
From the Executive Director's Office
CSMS 630 **Council Meeting**
CSMS 633 **Connecticut Stat**

general:

636 **Book Review**
637 **CSMS Physician**

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Human Immunodeficiency Virus–related Progressive Multifocal Leukoencephalopathy with a CD4$^+$ of 444 per mm^3: A Case Report

LINDA LEE, M.D., BARRY WU, M.D., HELENA BRETT-SMITH, M.D., AND PAUL FIEDLER, M.D.

ABSTRACT—A 47-year-old homosexual man with human immunodeficiency virus infection and CD4$^+$ cell count of 444 per mm^3, and with a viral load of 95,720 copies per mL, developed a rapidly progressive cerebellar lesion one month after undergoing coronary artery bypass graft. Diagnostic data were unremarkable with the exception of the magnetic resonance imaging that revealed multiple subcortical and cerebellar lesions consistent with a demyelinating process. The patient died within two months. Postmortem examination of the cerebellum revealed acute phase progressive multifocal leukoencephalopathy. This case demonstrates that multifocal leukoencephalopathy must be considered in HIV$^+$ patients in the setting of neurologic deterioration with radiographic evidence of demyelination regardless of CD4$^+$ count.

PROGRESSIVE multifocal leukoencephalopathy (PML) is a fatal demyelinating disease caused by a JC virus infection of oligodendrocytes. The incidence of PML has increased with the advent of human immunodeficiency virus (HIV) infection to about 4% in AIDS patients.[1] Patients with HIV and PML typically have a CD4$^+$ cell count <90 per mm^3 and a relentless deterioration of neurologic function with an average survival of three to four months after initial presentation.[2,3] We report a patient with HIV who developed PML with the highest CD4$^+$ count to date.

Case Report

A 47-year-old white homosexual male was diagnosed with HIV in 1987 after presenting with Guillain-Barré syndrome. He had a history of hypertension, coronary artery disease with angioplasty in 1992 and 1993, and shingles in 1993. He did well without opportunistic infections and refused antiretroviral therapy. In February 1996 his CD4$^+$ count was 955/mm^3 (28%) with a viral load of 95,720 copies per mL. He presented in May 1996 with unstable angina and underwent coronary artery bypass graft which was complicated by postpericardiotomy syndrome and left lower lobe pneumonia. He was readmitted one month later with dysarthria, right-sided weakness, and vertigo.

His physical examination was remarkable for cerebellar signs including a Romberg sign, right dysmetria, and ataxic gait. He had mild sensory impairment on his right foot and a Babinski reflex of the left. Mental status, cranial nerves, motor, and reflex examinations were otherwise unremarkable.

Admission laboratory results included a repeat CD4$^+$ count of 444 per mm^3 (22%), erythrocyte sedimentation rate of 64 mm per hour, negative VDRL and Lyme antibodies, and cytomegalovirus antigenemia of one cell per 200,000 white blood cells. Magnetic resonance imaging (MRI) and angiography showed a right cerebellar peduncle lesion and multiple subcortical white matter lesions without mass effect or ring enhancement consistent with a demyelinating process (Fig. 1). Initial cerebral

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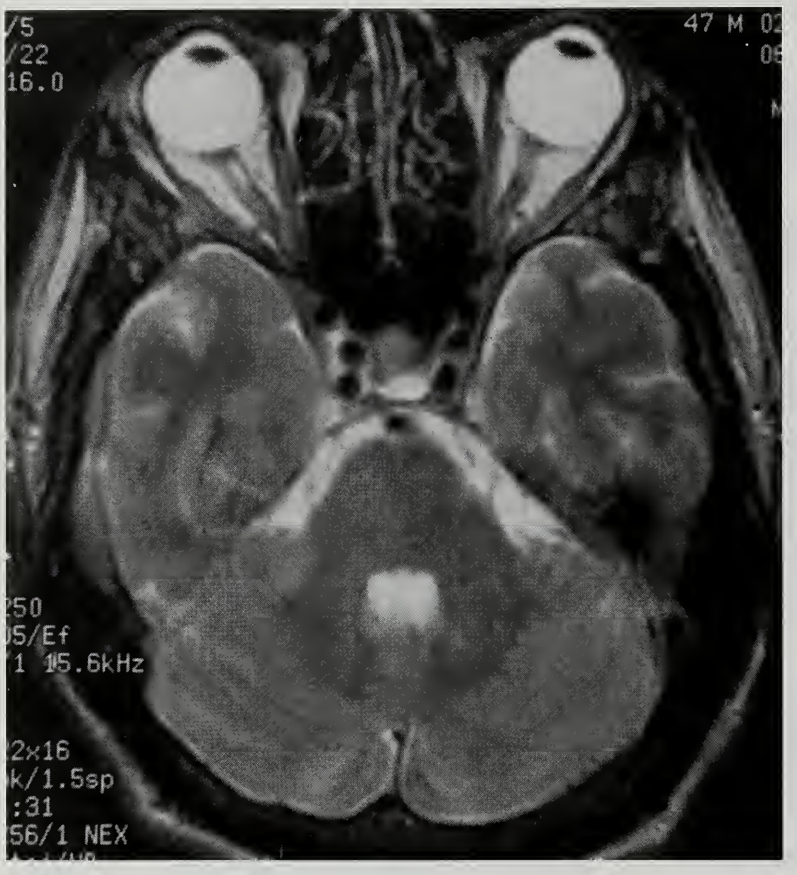

Figure 1.—Initial MRI of right cerebellar peduncle lesion.

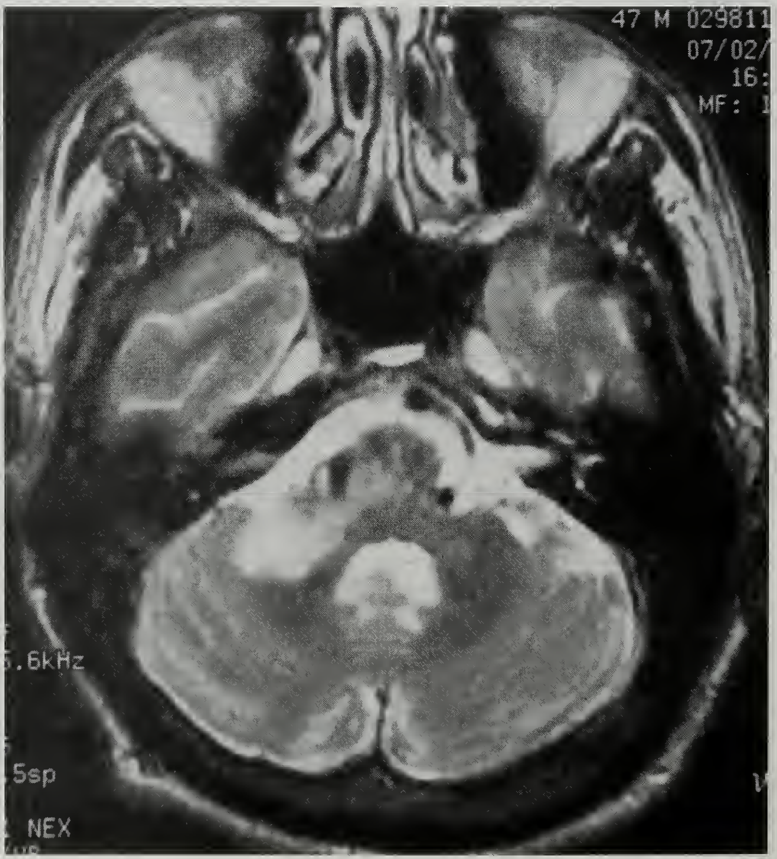

Figure 2.—One month later, MRI showed progression of right cerebellar lesion.

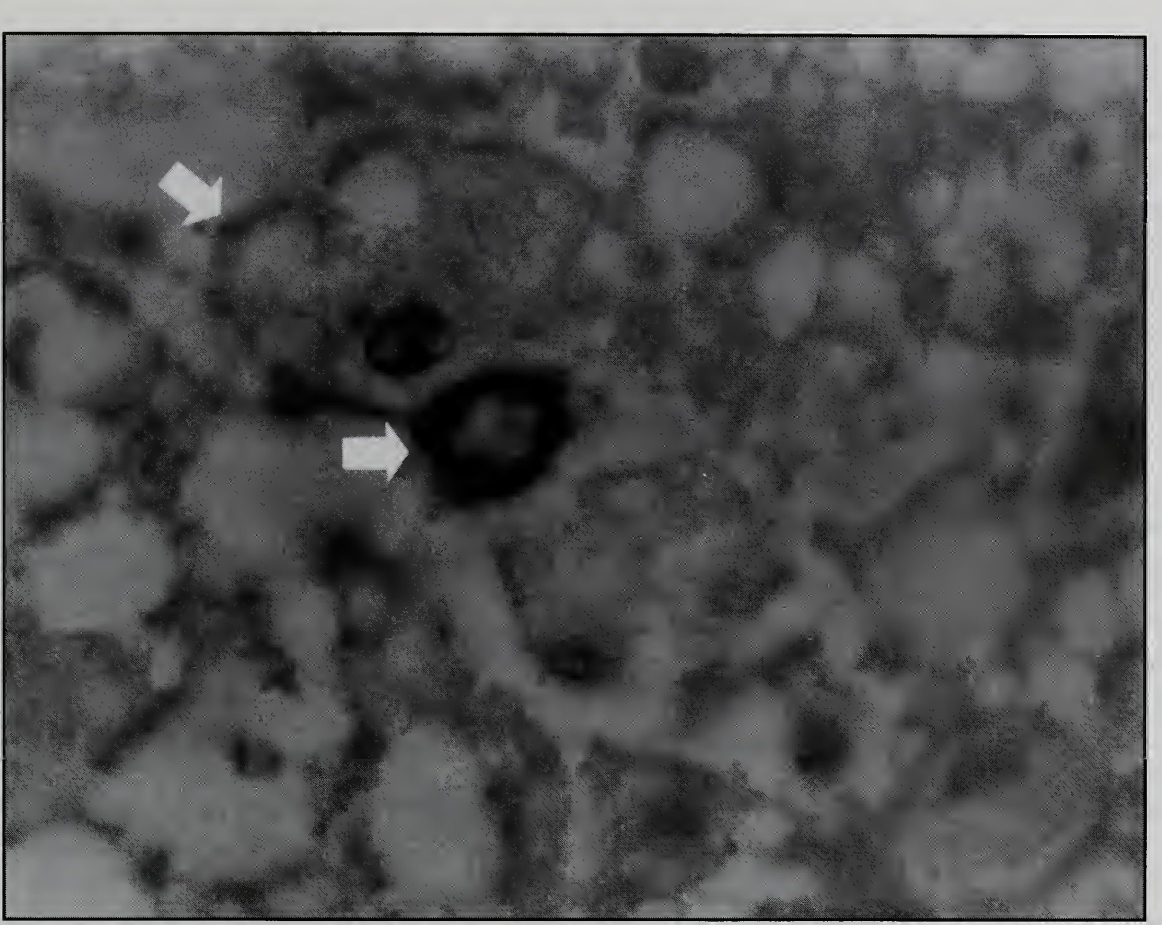

Figure 3.—JC virus infected oligodendroglial cell and foamy histiocytes in right cerebellar peduncle.

spinal fluid (CSF) was notable for protein of 83 mg/dL; VDRL, Lyme antibodies, cryptococcus antigen, India ink stain, bacterial, viral, and acid-fast bacillus tested cultures were negative. Subsequent CSF was sent for polymerase chain reaction to cytomegalovirus, varicella zoster virus, herpes simplex virus, and JC virus, all of which were negative.

Despite aggressive treatment with high-dose zidovudine, lamivudine, indinavir sulfate, and intravenous acyclovir, the patient's condition deteriorated rapidly. Follow-up MRI in July 1996 demonstrated a progressive lesion in the right cerebellar peduncle extending into the pons (Fig. 2). He died two months after initial neurologic presentation. Gross examination of the cerebellum was unremarkable. Microscopic examination revealed acute phase PML with demyelination and severe destruction of the white matter with replacement of the neutrophil by foamy macrophages. Atypical oligodendroglial cells with ground glass nuclei and eosinophilic nuclear inclusions were identified (Fig. 3). Features of other opportunistic infections, in particular cytomegalovirus and herpes, were not identified.

Discussion

PML is primarily seen in immunocompromised patients with lymphoproliferative or myeloproliferative disorders or AIDS. It is the only disease firmly associated with the JC virus. This virus is ubiquitous and up to 70% of adolescents have detectable antibodies to JC virus. It persists in the kidney and PML may result from reactivation and spread of the virus from the kidney or reactivation of a latent CNS infection.[1] The JC virus infects only oligodendrocytes and not neurons leading to cytolytic destruction of the cells and loss of myelin.[4] Lesions are often multifocal in the parieto-occipital and periventricular subcortical region.[4]

Patients present with a triad of symptoms of visual deficit, hemiparesis, and mental status changes.[5] MRI is superior to computerized tomography scan for detecting demyelinating lesions.[4] CSF findings are nonspecific with occasional mild elevation of protein. Brain biopsy is the gold standard for diagnosis. However, newer polymerase chain reaction (PCR) techniques may obviate the need for biopsies in approximately 80% of the cases.[1] Despite accurate and early diagnosis of PML, its course is a relentless deterioration of neurologic function with an average survival of three to four months after initial presentation.[2,3] Treatment has been attempted with nucleoside analogs including cytosine arabinoside, interferons, heparin sulfate, and corticosteroid. Currently there is no effective treatment for PML.

Clearly, PML may occur in HIV-infected patients with a high $CD4^+$ count. It is interesting that this patient had been doing well since being diagnosed with HIV in 1987 and then had a rapid decline in his $CD4^+$ count from February 1996 to June 1996, heralding his entry into the AIDS stage. It is well known that cardiac surgery has an immunosuppressive effect on patients. The coronary artery bypass graft surgery may have depressed the patient's immune system below the threshold that had been controlling the JC virus. Another interesting point is that despite the patient's high $CD4^+$ count, in February 1996 he had a high viral load as well. Perhaps the viral load rather than the $CD4^+$ count is the more relevant information in helping to assess a patient's risk for PML. Presently, in the setting of HIV infection with a deteriorating neurologic examination and radiographic evidence of demyelination, PML needs to be considered regardless of $CD4^+$ count.

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Intracranial Subependymoma

DAVID P. NEUMANN, M.D. AND HILARIO MARTINEZ, M.D.

ABSTRACT—Subependymomas most commonly appear as a mass in the fourth ventricle of adults; these tumors are rare but must be considered in the differential diagnosis of a lesion arising in this location. We report a case of a fourth ventricule subependymoma.

Case Report

A 31-year-old male presented with progressive dizziness, headache, nausea, and vomiting of approximately one-year duration. Physical examination revealed lateral nystagmus and papilledema.

Magnetic resonance imaging (MRI) revealed a lobulated, soft tissue mass arising from the fourth ventricle, extending through the foramen of Magendie and foramen magnum (Figs. A, B, and C). Prior to contrast enhancement, the mass exhibited a homogeneous signal isointense with the rest of the brain on T1-weighted images. On Proton-Density and T2-weighted images the mass of mildly hperintense. Following injection of contrast, mild homogeneous enhancement occurred.

At surgery, a lobulated irregular mass measuring 3.2 cm x 3.0 cm x 0.8 cm was resected from the fourth ventricle. The histopathologic examination revealed a poorly differentiated subependymoma.

Discussion

The differential diagnosis of a solid mass arising from the ependymal lining of the fourth ventricle in an adult includes subependymoma, metastasis, ependymoma, choroid plexus papilloma, and subependymal astrocytoma.

Subependymoma is a rare central nervous system (CNS) tumor considered to be biologically benign. Originating from the ependymal lining, these tumors may invade the adjacent parenchyma by direct extension. Subependymomas occur in middle-aged and elderly adults, and may occur anywhere along the ventricular pathway but are most frequently found in the lateral (60%) and fourth ventricle (40%). Those arising in the lateral ventricle often can be completely resected for definitive cure; however, those arising from the floor of the fourth ventricle are less easily resected because of the danger of cranial nerve or brain stem injury.[1]

The presence of calcification is a differentiating feature between lateral and fourth ventricular subependymomas. A fourth ventricle subependymoma is more likely to show calcification on unenhanced computed tomographic (CT) images than subependymomas of the lateral ventricle. These tumors arising from the fourth ventricle are usually large and lobulated and may extend into the foramen of Magendie and foramen magnum.[2] Obstructive hydrocephalus may develop with symptoms of vertigo, nausea, vomiting, and gait disturbance. The average age of patients in the symptomatic group is around 40 years; the average age of asymptomatic patients is about 60.

Subependymomas and ependymomas differ in their age at presentation and histologic findings. Ependymomas are more common in children with an age peak at one to five years of age. They arise from fusiform ependymal cells, and microscopic examination discloses a sparsely cellular neoplasm with a prominent fibrillary background; neovascularity, mitoses, and necrosis are absent.[3]

MRI is more accurate than CT in characterizing the lesion and determining its size, location, and extent. For these reasons, MRI is the preferred modality for surgical and therapeutic planning.

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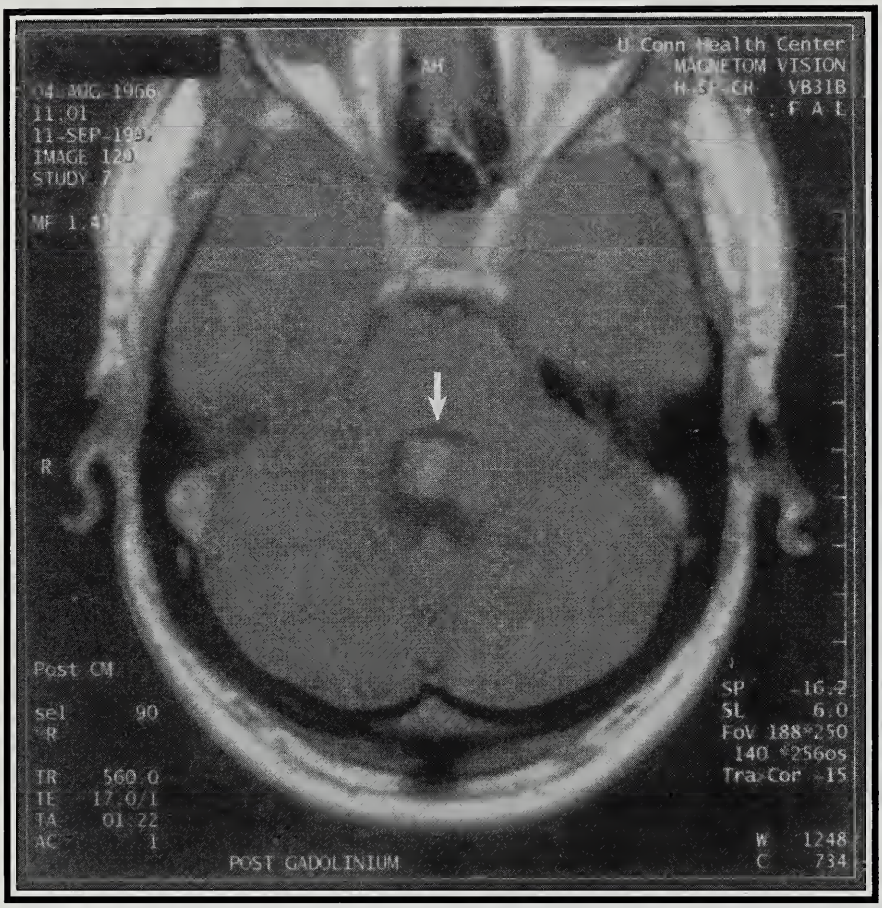
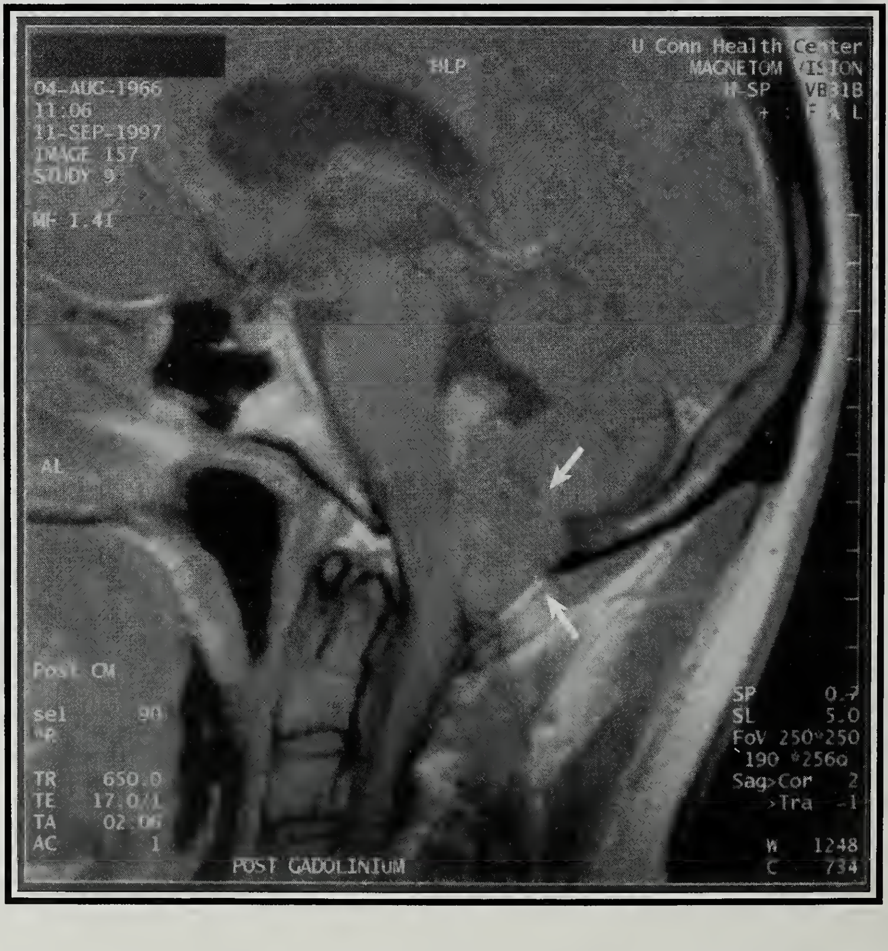
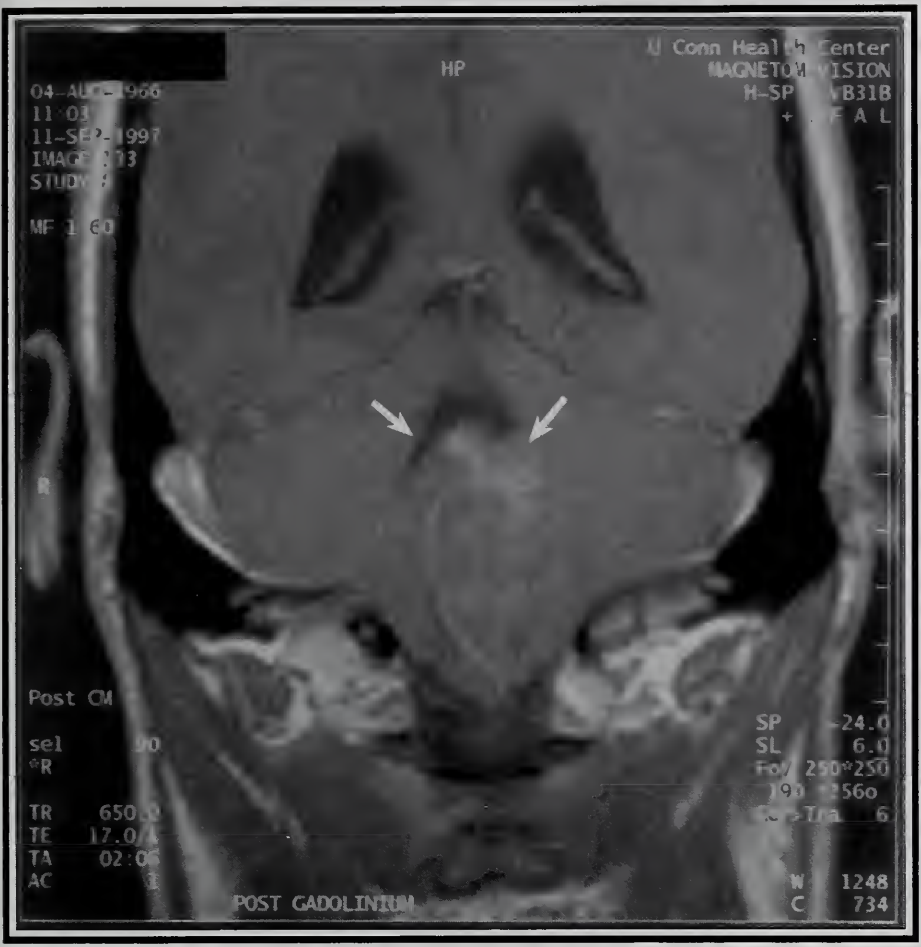


Figures A (left), B (below), C (right)—Axial, Sagittal, and Coronal postcontrast T1–weighted images, showing a lobulated subependymoma with mild contrast enhancement extending caudally through the foramen of Magendie and foramen magnum.

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Most subependymomas are typically homogeneous isointense masses on T1-weighted and mild hyperintense on T2-weighted images. Some signal heterogeneity may be present, reflecting multiple, small intramural cysts. Contrast enhancement in subependymomas is typically mild.[4] Ependymomas may show signal heterogeneity from necrosis, calcification (50%), and tumor vascularity. Moderate contrast enhancement is present.

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Thrombotic Thrombocytopenic Purpura Following Influenza Vaccination—A Brief Case Report

NAGARAJAN RAMAKRISHNAN, M.B.B.S. AND LEWIS P. PARKER, M.D.

Case Report

A 60-year-old female with past history of Reynaud's phenomenon and several positive antinuclear antibody tests, but without clinical autoimmune disease, was hospitalized four days after receiving an influenza vaccination. Her symptoms were marked fatigue, nausea, fever, diarrhea, oliguria, and ecchymoses. Initial physical examination revealed a fever (38° C) and echymoses in the lower extremities. Laboratory studies revealed thrombocytopenia (platelet count: 96,000), acute renal failure (blood urea nitrogen: 72 mg/dL, creatinine: 6.2mg/dL), and microangiopathic hemolytic anemia on blood smear examination (hematocrit: 28.4, lactic dehydrogenase: 5,787 IU/L). Immunoglobulins and complement levels were normal; antinuclear antibody positive (ANA) 1:1,280 (speckled pattern). Anti-ro antibody, anti-la antibody, anti-smooth muscle antibody, anti-ribonuclear protein antibody, anti-glomerular basement membrane antibody, and anti-neutrophil cytoplasmic antibody titres negative. Stool studies including *E. coli* 0157:H7 and shigella were negative. Renal biopsy revealed diffuse cortical necrosis, fibrin thrombi within glomeruli, and fibrin necrosis of capillary loops with extensive destruction of basement membrane and little fibrinoid necrosis (Fig. 1). These features were consistent with the clinical diagnosis of thrombotic thrombocytopenic purpura (TTP). Treatment included plasmapheresis and supportive care. During her rather prolonged hospital course, the patient developed fluctuating neuropsychiatric signs, including altered mental status, focal sensory, and motor signs. Computerized tomographic scan (CT) scans of her brain were unremarkable. Hemodialysis was initiated during the acute phase and maintenance therapy was by continuous ambulatory peritoneal dialysis. On discharge, the platelet count was 318,000 per cu mm and lactic dehydrogenase, 770 IU/L. The patient recovered completely.

Discussion

Thrombotic thrombocytopenic purpura (TTP) is characterized clinically by thrombocytopenia, microangiopathic hemolytic anemia, fluctuating neurological abnormalities, and fever. The etiology and pathogenesis of this remains unclear, but disseminated intravascular platelet aggregation from an intravascular stimulus has been observed. Immunological factors and associations have been studied and lead to the belief that immune complex formation due to antigenic stimuli may be one of the common mechanisms. Common antigenic stimuli include infections, which may be viral, bacterial, mycoplasma, rickettsia, or fungal.

Several reports have described association of TTP with autoimmune disorders, including lupus, rheumatoid arthritis, and polyarteritis.[1] Rothfield et al reported that the association of TTP and systemic lupus erythematosus (SLE) was rare. TTP has been classified as 1) acute, idiopathic TTP or primary TTP and 2) TTP associated with an immune disorder or secondary TTP.[2]

Infectious etiologies have been proposed, but no definite pathogen has been consistently isolated. Associations with preceding bacterial, viral, rickettsial, and fungal infections have been noted. In most of these cases TTP has occured days or weeks following the infection. Brown et al reported a case of TTP following influenza vaccination

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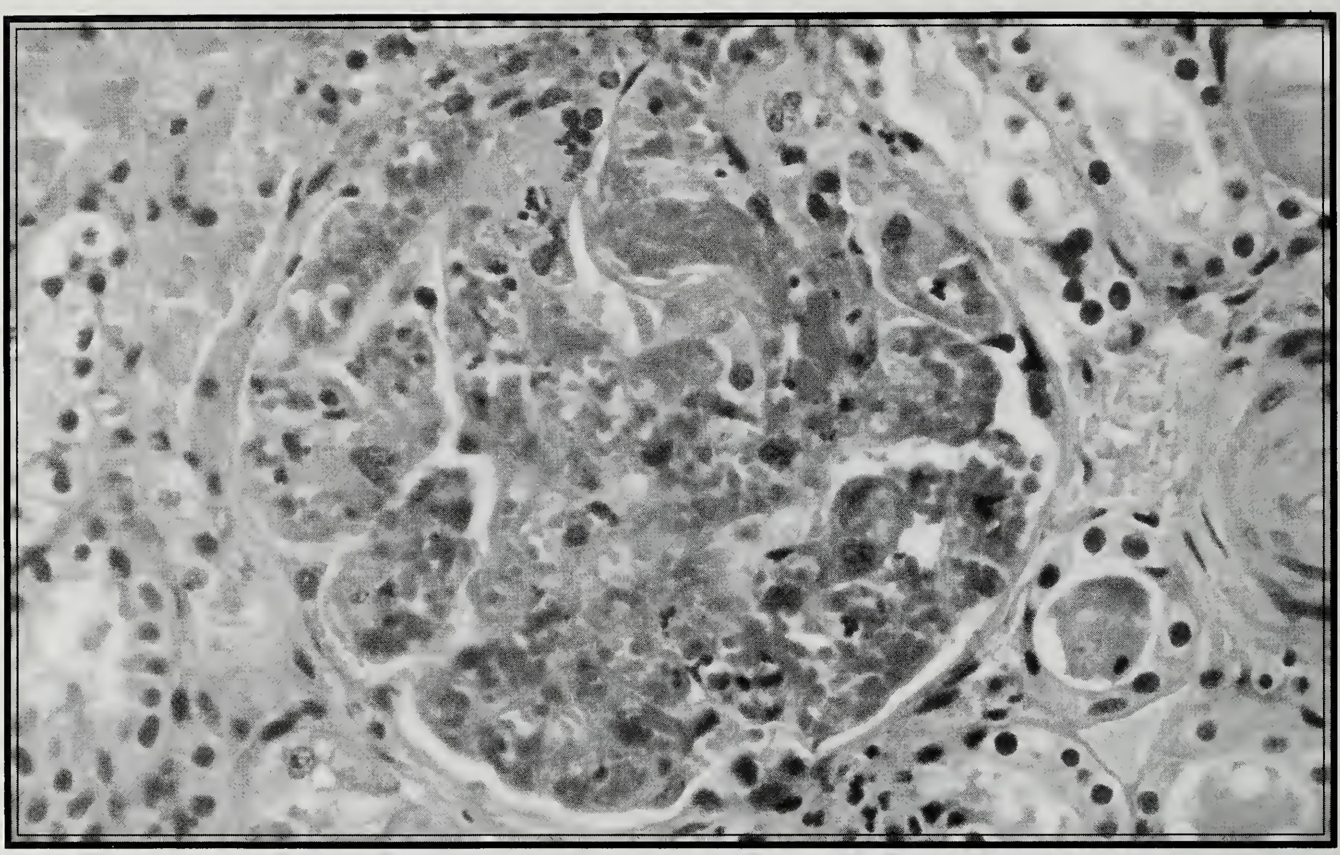

Figure 1.—Renal biopsy section showing diffuse cortical necrosis, fibrin thrombi within glomeruli, fibrin necrosis of capillary loops with extensive destruction of basement membrane with little fibrinoid necrosis.

in 1973,[3] and Frick et al reported a case triggered by typhoid vaccination. Cases of hemolytic-uremic syndrome, which some authors think is part of the spectrum of TTP, have been reported after triple, polio, measles, and smallpox vaccinations. Therefore, immune complex deposition due to antigenic stimuli, may well be one of the underlying mechanisms in the pathogenesis of TTP. It seems probable that the influenza vaccination was the stimulus for initiation of TTP in this case.

In our patient, although the past history of autoimmune phenomenon, Raynaud's syndrome, and the presence of ANA added to the complexity of understanding, the features were more consistent with primary TTP triggered by antigenic stimulus. This is supported by the rather dramatic response to plasmapheresis[4] and also normal complement levels which are more often seen in primary TTP.

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Important Advances in Clinical Medicine

Urology

DANIEL A. NACHTSHEIM, M.D., Section Editor

The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in urology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in urology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Urology of the California Medical Association, and the summaries were prepared under the direction of Dr. Nachtsheim and the Panel.

Informing Patients About the PSA Test: A New Requirement

A NEW law in California requires a physician who examines a patient's prostate gland to inform that patient of the prostate specific antigen (PSA) test if the patient falls into one of four broad categories. The 1997 law was created by Senate Bill 1, carried by California's Senate President Pro Tempore and written on behalf of a popular lobbyist who was seriously ill with prostate cancer (full text of SB 1 follows on page 167). Along with many other professional groups, California's medical association has clear a policy opposing statutory requirements for physicians that prejudice the exercise of their clinical judgment. In the circumstances of SB 1, the Medical Association worked with the author so that the final version of the bill no longer carried criminal penalties for noncomplying physicians and used Patient Section Criteria based on American Urological Association recommendations.

The enacted bill requires a physician to provide information on "the availability of appropriate diagnostic procedures, including but not limited to, the prostate specific antigen (PSA) test" if the physician for any reason examines the patient's prostate gland and any of the following applies: the physician believes it is medically necessary to provide the required information, or the patient is over 50 years of age, or manifests clinical symptomatology, or is at increased risk of prostate cancer.

Enactment of SB 1 should not create major changes in the practice of many California physicians who conduct a rectal exam for the purpose of detecting prostate cancer (as opposed to other possible reasons) and are already accustomed to discussing the potential risks and benefits of prostate specific antigen tests (PSA) and other diagnostic procedures for prostate cancer. This discussion usually includes reference to the current range of scientific statements on the appropriate use of PSA screening and facts most relevant for patient decision making. For example, the American Urological Association (AUA), which has revised its recommendations since SB1 became law, now endorses the American Cancer Society (ACS) recommendations. Their joint policy suggests offering a PSA test and digital rectal examination to men in approximately the same categories as outlined by SB 1, and also includes the statement that "Screening for prostate cancer in asymptomatic men can detect tumors at a more favorable stage (anatomic extent of the disease). There has been a reduction in mortality from prostate cancer, but it has not been established that this is a direct result of screening." The

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Bill Number: SB 1 Chaptered *(California)*
Chapter 11

Filed with Secretary of State May 20, 1997
Introduced by Senator Burton

December 2, 1996

An act to add Section 2248 to the Business and Professions Code, relating to health, and declaring the urgency thereof, to take effect immediately.

The People of the State of California do enact as follows:
Section 1. Section 2248 is added to the Business and Professions Code, to read:
2248. This section shall be known as, and may be cited as, the Grant H. Kenyon Prostate Cancer Detection Act.

(a) If a physician and surgeon, during a physical examination, examines a patient's prostate gland, the physician and surgeon shall provide information to the patient about the availability of apprapriate diagnostic procedures, including, but not limited to, the prostate antigen lPSA) test, if any of the following conditions are present:

(1) The patient is over 50 years of age.

(2) The patient manifests clinical symptomatology.

(3) The patient is at an increased risk of prostate cancer.

(4) The provision of the information to the patient is medically necessary, in the opinion of the physician and surgeon.

(b) Violation of subdivision (a) constitutes unprofessional conduct and is not subject to Section 2314.

Section 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:
Prostate cancer is currently a leading cause of cancer death in males in this country. In order to save as many people's lives from this deadly disease as soon as possible through public awareness of the availability of early detection procedures, it is necessary that this act take effect immediately.

National Cancer Institute finds insufficient evidence to recommend serum tumor markers such as the prostate specific antigen test, while the American College of Physicians (ACP) recommends an individualized decision of whether to screen a patient with a digital rectal exam or prostate specific antigen test. The ACP also suggests statements that could be given to the patient in making this decision. These include information on false-positive and false-negative results, the current lack of proof of the benefits of screening and aggressive treatment of prostate cancer, and the relatively high probability that further invasive evaluation will be required as a result of testing.

Some physicians laud SB 1's intent to increase discussion between physicians and patients of prostate cancer detection, but note that the law's requirements are too broad. A digital rectal exam that includes palpation of the prostate may be conducted on any patient to detect occult bleeding, to determine prostate position, or for other reasons unrelated to suspicion of prostate cancer. Physicians who ignore the prostate specific antigen test and other patient information requirements of SB 1 can be prosecuted by the Medical Board for unprofessional conduct. In a larger context, SB 1 is an example of elected officials responding to important medical issues by incorporating elements of clinical practice guidelines in effect at that time into legal requirements. It is important for physicians to understand these legal requirements while they seek to apply an evolving body of knowledge to the individual patient in their care.

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The Urethral Sling and Stress Urinary Incontinence

STRESS urinary incontence (SUI) affects between 15% to 60% of women, and has a tremendous impact on a woman's quality of life. Incontinence is either urgency or stress in nature. Urgency incontinence and mild SUI can be successfully managed in general with behavioral or anticholinergic treatment. Moderate to severe SUI is best managed by operative intervention. The following epitome discusses the role of urethral slings in the management of SUI.

Stress urinary incontinence is defined as the involuntary loss of urine related to increases in abdominal pressure resulting from activities such as laughing, coughing, lifting, and positional changes. Two factors are important to the development of stress urinary incontinence: urethral hypermobility and/or intrinsic sphincteric deficiency. Both factors commonly coexist and vary in their relative contribution in women with stress urinary incontinence. Hypermobility is the rotational descent of the proximal urethra and bladder neck into the vagina when there are increases in intra-abdominal pressure. Intrinsic sphincteric deficiency refers to a deficiency in urethral sphincter function, and is generally unrelated to urethral support. All operative procedures for stress urinary incontinence address either or both of these factors. The selection of a surgical procedure for stress urinary incontinence therefore depends on the relative contributions of urethral hypermobility and intrinsic sphincteric deficiency. Stress urinary incontinence related primarily to bladder neck hypermobility can commonly be corrected with routine bladder neck suspensions or urethral slings. If, however, urethral sphincteric deficiency is the primary cause of stress urinary incontinence, urethral bulking agents, artificial urinary sphincters, and sling procedures are appropriate. Of the treatment modalities mentioned, the urethral sling is the only procedure that addresses both the hypermobile urethra and intrinsic sphincteric deficiency. In addition, there has been a relatively recent realization that intrinsic sphincteric deficiency plays a more prominent role in stress urinary incontinence than previously believed. These two factors have led to an increase in the popularity of the urethral sling procedure.

In 1910, Goebell introduced the concept of a urethral sling by using reflected pyramidalis muscle as a bolster for the urethra. This is analogous to a leather seat supporting a child on a swing. Since then, several modifications using different autologous (eg, rectus fascia, fascia lata, vaginal wall) as well as synthetic (eg, mersilene, Gortex, Marlex) materials have been used. The utility of synthetic materials, however, is limited because of complications including bladder erosion, infection, and fistula formation. There has been a recent interest in the use of homologous tissue for urethral slings, and the initial results appear promising.

Approaches to the urethral sling can be classified as transabdominal, transvaginal, and a combination of both. There is no compelling evidence that one approach is superior to the others. The type of operation is best determined by surgeon preference and experience. Regardless of approach, the principles are the same: a broad base support directly under the urethra, which is placed with only minimal tension.

The American Urologic Association Female Stress Urinary Incontinence Clinical Guidelines Panel conducted a comprehensive review and in-depth analysis of published outcome data pertaining to different surgical procedures for urinary incontinence. This panel concluded that urethral slings, along with retropubic bladder neck suspensions, are the most efficacious procedures for long-term success in the treatment of urinary incontinence secondary to urethral hypermobility. They report a greater than 85% probability of improvement of urinary incontinence at 48 months or longer with the use of urethral slings. Although outcome literature is sparse for patients with intrinsic sphincteric deficiency treated with slings, it was the panel's opinion that this procedure is also an effective type of treatment for intrinsic sphincteric deficiency patients. Possible complications of sling procedures include prolonged urinary retention, urgency, and urgency-related incontinence. The risk of postoperative urgency ranges from 7% to 46% and can be quite debilitating to the patient. Urinary urgency is best managed with behavioral training (fluid moderation, timed voiding, pelvic floor exercises) or anticholinergic medications. In general, if urgency is present preoperatively, there is a significant risk that these symptoms will persist postoperatively. The risk of permanent retention, however, is low at less than 5% and can be managed with clean intermittent catheterization or urethrolysis.

The urethral sling addresses urethral hypermobility and may address intrinsic sphincteric deficiency. This versatility, along with excellent cure rates and low complication rates, have led many to apply this operation to most types of stress urinary incontinence to those patients who have opted for surgical intervention.

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Peyronie's Disease: A Difficult Sexual Dysfunction Problem

PEYRONIE'S disease is a physically and psychologically devastating problem that affects up to 2% of men. Those affected are primarily between the ages of 40 and 60. Peyronie's disease is manifested by fibrous, inelastic scar tissue involving the tunica albuginea of the penis, the fibrous jacket surrounding the spongy, vascular tissue of the corpora cavernosa, which expands during the development of an erection. The inelastic scar is palpable in the flaccid penis, but a penile deformity such as bending, narrowing, hinging, and/or shortening can be visible when the penis becomes erect. Painful erections may occur particularly in the early phase of the disease. All of these changes can result in difficulty with vaginal penetration and may be further exacerbated by concomitant disorders such as diabetes, hypertension, elevated serum lipids, or a smoking history that could cause decreased arterial inflow or venous leakage.

The disease received its name in the 1740s from Francois de la Peyronie, who was the first surgeon to King Louis

XV. Despite all treatment options available since then, it still remains a therapeutic dilemma. Most commonly, the characteristic Peyronie's plaque is found on the dorsum of the penis causing an upward curvature during erection. However, other plaque locations can occur, resulting in various penile deformities. To understand how the erection deformity occurs, imagine the effect of placing a piece of tape on a child's balloon. As the balloon expands, it will curve around the inelastic segment caused by the tape.

The cause of Peyronie's disease remains an enigma. There have been many theories, including sexually transmitted, inflammatory, or autoimmune. The mechanical injury theory suggests that trauma to the erect penis activates the disease process. More current proposals suggest that Peyronie's disease may, in fact, be a wound healing disorder, much like a keloid or hypertrophic scar. It has been noted in patients with Peyronie's disease that elastin, the protein which allows for normal tunical expansion, is decreased or abnormal in the outer jacket. Therefore, pressure on the erect penis during intercourse can stretch the tunical fibers, and, due to the decreased tolerance to stress, a delamination or fracture injury typically involving the septal and inner circular fibers of the tunica may occur. Following injury, the release of cytokines activate fibroblast proliferation and collagen, the primary extracellular matrix component of a Peyronie's plaque, is produced. Disregulation in the genetic code could cause a loss of balance between scar formation and remodeling. The result is the deposition of an exuberant scar which does not remodel properly.

Although Peyronie's disease may resolve spontaneously, this appears to be uncommon (around 15%). Treatment options include conservative therapy, which is the treatment of choice for many patients (30%). This would include observation of the man who has minor curvature (eg, <30°), which does not interfere with his ability to have sexual relations, and neither he nor his partner experience pain during intercourse. This patient should be reassured that this is a disease that will not degenerate into malignancy. Oral therapies have also been used, although there is no clear, reliable, efficient choice. The most common oral medications currently used are vitamin E, Potaba (potassium aminobenzoate), and colchicine. Drugs injected directly into the plaque have also been used, including steroids, verapamil, and collagenase. The use of steroids has fallen out of favor due to significant failure rates and uncommon but worrisome side effects, including local tissue atrophy and adrenal suppression. Verapamil, a calcium channel blocker known to change fibroblast function *in vitro* in doses that can be achieved by intralesional administration, has been used clinically with reported success.

Fibroblasts exposed to calcium channel blockers change from stimulating a synthetic cell manufacturing scar to more of a degradative process. Clinical trials with intralesional verapamil injections into a Peyronie's plaque show positive effects in about 60% of patients with respect to deformity improvement and in 75% by subjective report. Over 70% of patients have improved sexual function. For those patients with acute disease associated with painful erections, 97% have rapid resolution of their penile pain with one to four injections. Typically, 10 mg of this drug diluted up to 10 ccs with saline is injected into the Peyronie's plaque after performing a buprivical penile block to anesthetize the penis (6-12 sessions). No cardiovascular or hypotensive events have been noted. The primary side effect is ecchymosis due to the puncturing of the subcutaneous tissues, 2-3 punctures in the skin and 200-300 in the plaque. It appears that modifiers of cytokine and fibroblast function may be the future for therapy of early Peyronie's disease.

Surgery is used for patients with more advanced deformity and/or decreased rigidity. Tunica plication is a type of surgery that straightens the penis by shortening the long side (convex) of the penis to equal the shorter side. Plaque incision or excision has also been employed successfully. The defect created in the tunica is patched with a variety of autogolous tissues, including dermis, vein, and temporalis fascia. In the man who has penile deformity as well as insufficient rigidity, placement of a penile prosthesis is indicated.

In conclusion, therapeutic advances have not resulted in a reliable cure to this problem, probably because of an incomplete understanding of the basic pathophysiology of Peyronie's disease. Recent advances in the understanding of wound healing and its disregulation may offer new treatment options such as modifiers of cytokine and fibroblast function. Eventually, multimodality protocols may be developed that might include combined collagenase/verapamil intralesional injections with concurrent oral therapy, such as colchicine, to stabilize or improve the deformity. Of course, for those patients who do not succeed with conservative therapy, surgery may be offered. Surgery is also indicated for patients with severe deformity, extensive plaque calcification, those who have failed conservative therapy or have erectile failure, or any patient who insists upon a more rapid, reliable result.

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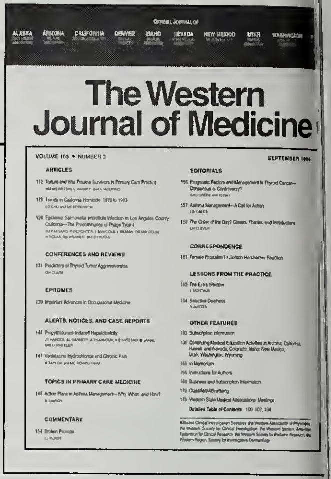

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MORBIDITY AND MORTALITY WEEKLY REPORT

Changes in Mortality From Heart Failure— United States, 1980–1995

HEART failure is a disabling chronic disease and the leading principal diagnosis for hospitalization among older adults. Among the estimated 4.8 million U.S. residents who have heart failure, 70% are aged ≥ 60 years.[1] During the past decade, the number of hospitalizations for heart failure has increased among Medicare beneficiaries,[2] and these numbers are expected to increase with progressive aging of the U.S. population even though the case-fatality rate for heart failure is high. This report summarizes trends in mortality from heart failure in the United States for 1980–1995 and presents state-specific death rates for 1995 (the most recent year for which such data are available).

National mortality statistics are based on information from death certificates filed in state vital statistics offices and are compiled by CDC. Cause-of-death statistics are based on the underlying cause of death* recorded on the death certificate by the attending physician, medical examiner, or coroner in a manner specified by the World Health Organization and endorsed by CDC. Population estimates from the Bureau of the Census were used to calculate death rates for the U.S. population. Heart failure deaths were defined as those for which the underlying cause of death listed on the death certificate was *International Classification of Diseases, Ninth Revision* (ICD-9), code 428. This category includes congestive heart failure (ICD-9 code 428.0), left heart failure (428.1), and unspecified heart failure (428.9). Age-adjusted estimates were standardized to the 1970 U.S. population. Race-specific rates were limited to blacks and whites because numbers for other racial/ethnic groups were too small for meaningful analysis. The average annual percentage change in mortality from 1988 through 1995 was calculated as the 1995 rate minus the 1988 rate divided by the 1988 rate divided by seven and multiplied by 100.

From 1980 to 1995, the number of deaths with heart failure as the underlying cause increased from 27,415 to 46,484; in 1995, approximately 43,600 (94%) of these deaths occurred among adults aged ≥65 years. The overall rate changed from 10.3 in 1980 to 11.7 in 1995. Death rates for heart failure per 100,000 population were directly proportionate to age. For example, in 1995, age-specific rates were 633.5 for persons aged ≥ 85 years, 130.8 for persons aged 75–84 years, and 32.2 for persons aged 65–74 years. The rate for persons aged ≥ 85 years increased during 1980-1988 but declined slightly during 1989–1992 (Fig. 1). Similar small declines also were observed during the same period for adults aged 75–84 years and those aged 65–74 years.

For persons aged ≥ 65 years, age-adjusted death rates for heart failure increased during 1980–1988 and declined after 1988 in each racial and sex group (Fig. 2). Age adjusted rates for the U.S. population aged ≥ 65 years declined from 116.9 per 100,000 standard population in 1988 to 107.6 in 1995 (an average annual decline of 1.1% compared with 1988 rates). Among persons aged ≥ 65 years, age-adjusted rates for 1995 were 126.1 for black men, 117.0 for white men, 107.6 for black women, and 101.2 for white women. The largest average annual percentage decline compared with 1988 rates occurred among black men (3.0% per year), followed by black women (2.2%), white men (1.7%), and white women (0.5%). Because of greater declines in death rates for heart failure among black adults, from 1980 to 1995 the black:white ratio for men narrowed from 1.3:1 to 1.1:1 and for women from 1.4:1 to 1.1:1.

In 1995, age-adjusted death rates for heart failure among all ages varied substantially among the states and ranged from 3.4 (New Hampshire) to 29.7 (Mississippi) (Table 1). For persons aged ≥ 65 years, age-adjusted rates for 1995 ranged from 30.7 (New Hampshire) to 255.6 (Alabama).

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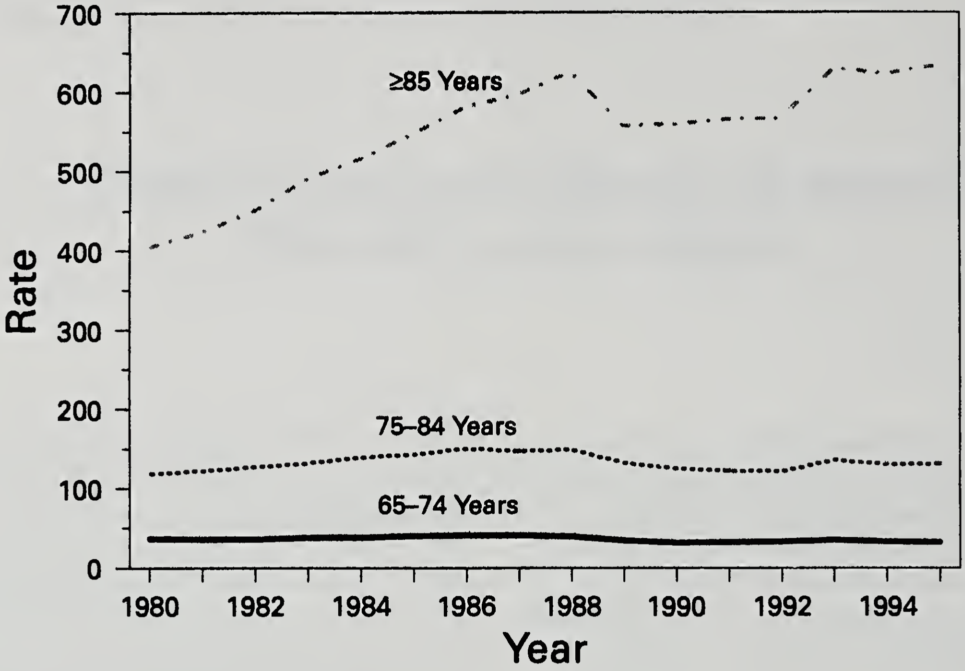
*Defined by the World Health Organization's *International Classification of Diseases, Ninth Revision,* as "(a) the disease or injury which initiated the train of morbid events leading directly to death, or (b) the circumstances of the accident or violence which produced the fatal injury."

Reprinted from the *Morbidity and Mortality Weekly Report*, 7 August 1998; vol. 47, no. 30, Centers for Disease Control (CDC), National Institute for Health (NIH).



†*International Classification of Diseases, Ninth Revision,* code 428.

Figure 1.—Age-specific death rate per 100,000 population for heart failure† for persons aged ≥ 65 years, by age group and year—United States, 1980–1995.

Reported by: G.A. Haldeman, A. Rashidee, R. Horswell, Louisiana Health Care Review, Inc., Baton Rouge, Louisiana. Cardiovascular Health Branch, Division of Adult and Community Health, National Center for Chronic Disease Prevention and Health Promotion, CDC.

Editorial Note: The findings in this report are consistent with a previously observed increase in age-adjusted death rates for heart failure during 1980–1988[3] that was followed by a decline after 1988. The decline suggests improved survival of older adults with heart failure or misdiagnosis of the underlying cause of death among adults with heart failure. For example, heart failure is five to six times more likely to be reported as a contributor rather than as the underlying cause of death on the death certificate.

Adults who survive a myocardial infarction or other hypertension-related diseases remain at increased risk for heart failure as they age. Among Medicare beneficiaries who are hospitalized for heart failure, hypertension is the secondary condition most commonly observed among black adults, and coronary heart disease is most common among white adults.[2] Declines in death rates for heart failure during 1988–1995 among black adults and white men may reflect improved early detection of and changes in the therapeutic management of patients with hypertension,[4] myocardial infarction,[5] and heart failure.[6–9] Since 1988, declines in death rates were greater among black adults than among white adults. Narrowing of the black-white ratio for heart failure mortality may reflect improved control of hypertension and access to medical care among older black adults.

Low numbers of deaths in some states should be interpreted with caution because they may reflect random variation. However, variations by state in death rates for heart failure also may reflect regional differences in the prevalence and treatment of predisposing conditions (eg, hypertension, myocardial infarction, and other heart diseases) and variations in access to early diagnosis and therapeutic management of heart failure. Medical specialty differences in treating heart failure[9] and state variations in mortality from heart failure suggest that national professional education initiatives may be needed to ensure that the clinical practice guidelines for evaluation and care of patients with heart failure are followed appropriately by all physicians to improve survival and reduce the risk for hospitalization through consistent pharmacologic management of this condition. Peer review organizations in states such as Louisiana[10] have begun to assess statewide practices of evaluating and treating heart failure as the first stage for implementing standardized quality improvement efforts that will target the hospital care of all Medicare patients with heart failure. Historically, the treatment

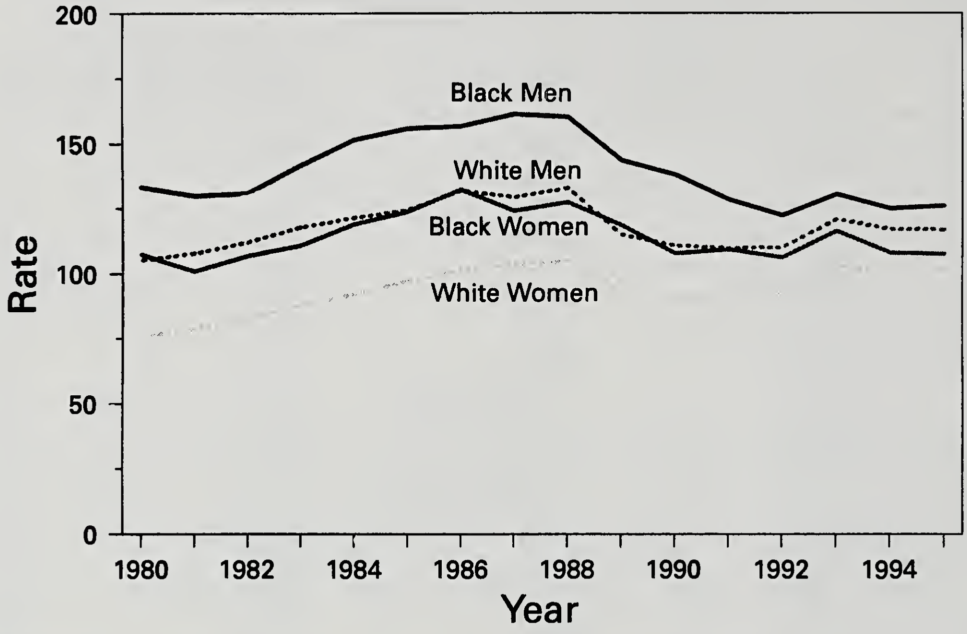
Table 1.—Number of deaths from, and age-adjusted rates for heart failure,* overall[†] and among persons aged ≥65 years,[§] by state—United States, 1995

	All ages		Persons aged ≥65 years	
	No.	Rate	No.	Rate
Alabama	1,825	28.8	1,668	255.6
Alaska	34	12.3	29	114.1
Arizona	463	7.4	431	67.3
Arkansas	1,077	25.1	1,007	226.0
California	2,277	5.5	2,148	52.0
Colorado	643	13.9	615	132.6
Connecticut	591	9.9	565	93.8
Delaware	124	12.4	114	111.3
District of Columbia	101	11.9	88	96.8
Florida	1,150	3.7	1,099	34.5
Georgia	1,405	17.1	1,277	154.4
Hawaii	87	5.5	78	46.9
Idaho	234	14.3	227	137.8
Illinois	2,619	14.6	2,460	134.0
Indiana	1,548	17.5	1,475	165.3
Iowa	202	3.6	200	33.0
Kansas	811	16.8	780	157.8
Kentucky	1,222	21.8	1,127	196.6
Louisiana	932	16.9	826	146.2
Maine	276	12.9	264	119.7
Maryland	660	10.2	614	94.4
Massachusetts	1,551	13.8	1,502	132.6
Michigan	1,804	12.9	1,706	121.5
Minnesota	884	11.1	864	107.4
Mississippi	1,124	29.7	987	247.6
Missouri	1,252	13.4	1,173	121.3
Montana	214	15.3	204	142.3
Nebraska	534	18.3	495	159.5
Nevada	291	17.3	265	158.3
New Hampshire	56	3.4	52	30.7
New Jersey	1,225	9.7	1,156	89.0
New Mexico	250	11.8	231	108.8
New York	2,272	7.7	2,148	71.0
North Carolina	1,048	10.3	964	93.7
North Dakota	176	13.4	172	129.6
Ohio	2,203	12.4	2,100	118.0
Oklahoma	1,087	19.8	1,021	181.5
Oregon	619	11.6	595	109.5
Pennsylvania	2,940	13.1	2,802	122.0
Rhode Island	66	3.5	63	32.4
South Carolina	702	15.1	628	131.8
South Dakota	197	13.5	190	127.1
Tennessee	504	6.7	458	58.6
Texas	2,764	12.4	2,517	112.5
Utah	335	16.1	320	155.1
Vermont	98	10.3	97	102.9
Virginia	1,276	15.3	1,175	140.4
Washington	786	10.1	757	97.2
West Virginia	551	17.0	529	161.8
Wisconsin	1,304	14.7	1,252	138.1
Wyoming	84	12.9	81	123.4
Total	**46,484**	**11.7**	**43,596**	**107.6**

**International Classification of Diseases, Ninth Revision,* code 428.

[†] Per 100,000 population; standardized to the 1970 Bureau of the Census population.

[§] Per 100,000 population; standardized to the 1970 Bureau of the Census population aged ≥65 years.



**Per* 100,000 population, standardized to the 1970 Bureau of the Census population aged ≥ 65 years.

†*International Classification of Diseases, Ninth Revision,* code 428.

§Data for racial/ethnic groups other than blacks and whites were too small for meaningful analysis.

Figure 2.—Age-adjusted death rate* for heart failure† for persons aged ≥ 65 years by race,§ sex, and year—United States, 1980–1995

of heart failure included combinations of diuretics and digitalis. Guidelines for clinical practice[7,8] recommend a trial of angiotensin-converting enzyme (ACE) inhibitors for heart failure patients with left ventricular systolic dysfunction (ie, an ejection fraction of ≤ 40%), unless specific contraindications exist, and use of diuretics for patients with volume overload. Digoxin should be initiated with ACE inhibitors and diuretics in patients with severe heart failure and should be added in patients who remain symptomatic despite optimal management with ACE inhibitors and diuretics. Although mortality for heart failure is declining, an increasing number of older adults with heart failure will have a substantial impact on national health-care resources and expenditures. Despite potential progress in the treatment of heart failure, public health and clinical efforts should continue to target the prevention and treatment of high blood pressure and acute myocardial infarction—the two major, preventable underlying conditions associated with increased risk for heart failure. Primary prevention of heart failure includes adherence to everyday health practices associated with preventing hypertension and myocardial infarction (eg, reduced dietary fat and/or sodium intake, moderate alcohol intake, weight maintenance, regular physical activity, and nonsmoking or smoking cessation). In addition, adults with hypertension should control blood pressure levels by improving daily health practices and using antihypertensive medications to prevent the development of heart failure.

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The Robert U. Massey History of Medicine Society is an association of individuals interested in presentations and discussions on the history of medicine. The society seeks to foster an understanding of medicine's historical context and an appreciation for the cultural and social settings in which medical developments have taken place. The society also seeks to encourage health sciences students to acquire an appreciation for their historical heritage.

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The society is affiliated with the University of Connecticut Health Center and is open to those who have an interest in the history of medicine. A roster of members is maintained in the Department of Community Medicine and Health Care. Those who wish to be included on the membership roster should notify this department to be included on the mailing list for society lectures. The willingness of members to present lectures or recommend speakers contributes to the society's ability to maintain community interest and to attract new members.

The society meets the 2nd Wednesday of the month at 5 P.M. in Lecture Room A of the University of Connecticut Health Center. *For further information, contact:* Theo Ungewitter, Department of Community Medicine, University of Connecticut School of Medicine, 263 Farmington Avenue, Farmington, CT 06030-1910; (860) 679-2356; *email:* ungewitter@nso.uchc.edu

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James Bryan Herrick: A Man of Intellectual Muscle

SUNDARAM V. RAMANAN, M.D.

ABSTRACT—James Bryan Herrick was an American physician who made several contributions to clinical medicine. Three of his most important observations are described.

> I was born in the village of Oak Park Illinois on August 11, 1861. My mother's odd name of Kettlestrings indicated that one of my ancestors was a bookbinder. A "kittlestring" is a cord that binds together a certain number of pages of a book.[1]

THUS began the life of James Bryan Herrick, a physician of remarkable intellect and perspicacity. A man of culture, inquisitiveness and, above all, a believer in the importance of clinical skills in diagnosis, his scholarship extended far beyond medicine. Most cardiologists today know of Herrick's contribution to the understanding of nonfatal coronary thrombosis, a disorder that, until then, had been regarded as being universally fatal. Two years earlier, he had observed "peculiar elongated red blood corpuscles" in a severely anemic patient. Describing his observations in a classic paper, he included "details that may seem nonessential," expressing the hope that comparison with similar cases in the future "may help in solving the problem."[2] Few physicians, however, are aware of what I believe to be Herrick's greatest contribution to the practice of day-to-day medicine, the recognition of chronic blood loss as a cause of anemia.[8]

Early in his education, the young Herrick developed a deep interest in the Latin, Greek, and German languages. His interest went far beyond the works of Virgil and Cicero, and he delved with vigor into the writings of Pliny, Catullus, and Tacitus. He had the makings of a classical scholar, and his decision to follow a career in medicine was more pecuniary than humanitarian: "The prospect of a happy, successful married life seemed greater if I became a physician rather than a teacher." He decided to enter medical school because

> Most young men who wanted to become physicians instead of quacks took up the study of medicine in some medical school, some of which were good, some bad, and some indifferent.[1]

A curious feature of the times was that a year of "practical experience" was needed before formal lectures. For this, a prospective student was required to register his name with any doctor, who then became his "preceptor." In 1886 at the end of a year of practical experience, he was admitted to Rush Medical College in Chicago. Lectures consisted of two years of 20 weeks each, covering seven topics: anatomy, physiology, chemistry, materia medica, obstetrics, surgery, and practice. The lectures were supplemented with "a little dissecting, and two or three amphitheater clinics each week." After a not-too-difficult oral examination, if all went well as it usually did, the new graduate was let loose to practice on his fellow creatures with the blessings of his Alma Mater. Graduation was followed by a highly-coveted internship at Cook County Hospital. While interns learned much from their senior colleagues, their greatest source of knowledge was the 'dead-house,' as it was then known. The dead house was always packed with knowledge-hungry students and young physicians, waiting to see exposed before them the diagnostic successes, failures, and foibles of their senior staff.

Private practice was Herrick's next venture: "There was a thrill in feeling that I was free and nobody's hired

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man. I learned later that there was a good deal of delusion about this." As a general practitioner, he "punctured eardrums, lanced tonsillar abscesses, set fractures, and even amputated the foot of a policeman." Soon, however, he dispensed with gynecology "as this branch of medicine has been most disagreeable to me." He later dropped all his other surgical endeavors, limiting himself to what we now call internal medicine.

A few years after graduation, Herrick was, as he put it, "attacked by the fever that was prevalent in the '90s that induced young doctors to go to Europe for postgraduate work." At that time it was considered imperative that any physician who could afford to do so must spend some time visiting hospitals in Europe to sharpen his diagnostic skills. The postmortem exercises to which I have referred played an important part in education. In an era when therapy had little effect on the course of disease, patients were either destined to recover or doomed to die. When the death of a patient was imminent, news rapidly spread, and the postmortem examination was awaited with feverish excitement. Yesterday, as today, there were physicians who freely admitted their errors, those who denied them even in the face of irrefutable evidence, and those who truly came to learn.

Herrick returned to Chicago after spending some time in Prague, Munich, and Vienna, still dissatisfied with the extent of his learning.

> For some time, I had realized that chemistry was destined to play an important role in Medicine. It was increasingly difficult for me to understand articles that involved the application of biological, physical and organic chemistry.

At the age of 43, he sharply cut back on his practice, and attended the University of Chicago five mornings a week to learn physical chemistry under Julius Stieglitz and organic chemistry under the tutelage of J.U. Nef. Two years of study did not satisfy him, and feeling that he could make no further progress in this country, he sought a position with Emil Fischer who had just been awarded the Nobel prize for his work on sugars. In Berlin, Fischer had now turned his attention to the structure of polypeptides, and this is exactly what Herrick wanted. He returned to Chicago invigorated, and it was in the next few years that he made what I believe to be his most important contributions to clinical medicine.

An editorial in *The Annals of Internal Medicine* relating to Guidelines for Risk Stratification in Myocardial Infarction opens with the statement "Since Herrick's classic description of acute myocardial infarction was published..." and then goes on to discuss the Clinical Guidelines outlined in the same issue of the journal.[3] By 1910 Herrick had written several papers on heart disease and, by his own account, was "pretty familiar with the literature of heart disease and had quite an extensive clinical experience with it." The first patient in whom Herrick made the antemortem diagnosis of coronary thrombosis was attended with much uncertainty. Doctor Murphy, a colleague also called in consultation, spent a sleepless night with Herrick in a hotel room where the conversation went something like this:

> Herrick, are you awake? Say, are you sure about there being no pneumothorax?
>
> And, a few minutes later:
>
> Murphy, do you think this might be an acute pancreatitis? Or possible a strangulated diaphragmatic hernia?[4]

Nevertheless, Herrick did make a firm clinical diagnosis of coronary thrombosis. When the patient died a few days later and the pathologist rather mockingly asked what he might expect to find at the autopsy, Herrick replied, "Look for a clot in the coronary artery." The pathologist later responded: "The clot was in the coronary artery all right. But how, in God's name, did you guess it?"

By May 1912 Herrick felt much more confident of diagnosing coronary thrombosis antemortem. All agog with excitement, he presented his views to his colleagues at the Association of American Physicians, expecting a rapturous response. It fell "like a dud." In Herrick's own words:

> You know, I've never understood it. In 1912, when I arose to read my paper at the Association, I was elated, for I knew that I had a substantial contribution to present. I read it, and it fell flat as a pancake. No one discussed it except Emanuel Libman, and he discussed every paper read there that day. I was sunk in disappointment and despair.... I can still see the quizzical look on Charlie Mayo's face as, from a front seat, he listened to, but was evidently not converted by my sermon.

Undaunted, Herrick published his observations later that year in what is now recognized a seminal paper. Refuting the view that coronary arteries are end arteries incapable of developing collaterals, he analyzed clinical and experimental data supporting his view that sudden obstruction of a coronary artery may occur without sudden death.

> Obstruction of the coronary artery has long been regarded as a serious accident ... but there are reasons for believing that even large branches of the coronary arteries may be occluded without sudden death.[5]

Herrick then stressed the importance of dividing patients into "groups," realizing full well that such a division "must be artificial and ... imperfect." Herrick's "Groups" form the basis of today's risk stratification in the management of ischemic heart disease and, more recently, hypertension as recommended in the 1997 Guidelines.[6] Finally, Herrick discussed the difficulty of differential diagnosis and the distinction of coronary thrombosis from "surgical accidents," ie, intra-abdominal causes of chest pain.

In 1918 Herrick acquired an Einthoven string galvanometer, the precursor of the electrocardiograph, as did many of his contemporaries. Fred M. Smith induced coronary occlusion in dogs, recorded cardiograms, and carried out autopsy studies on the animals, confirming Herrick's clinical observations. Then, as now, a presentation with "a lantern slide, or a graph, or an experiment on a dog in a laboratory" attracted greater attention than "mere observations at a bedside." This provoked Herrick to remark wistfully, "Why is it that work done in a laboratory on a dog attracts more attention than that done in the ward on a human being?"[7]

In 1904 a 20-year-old "intelligent Negro" from Grenada presented to Herrick with weakness, lymphadenopathy, and jaundice, a history of similar episodes in the past. On examination, lymph glands were palpable at all sites, and "The heart reminded me of a heart under strong stimulation, though no history of ingestion of a stimulant of any kind was obtainable."[2] The only other physical findings of interest were numerous scars confined to the lower extremities. These the patient ascribed to having had yaws a few years earlier. The counterpart of today's toxicology screen was negative. The hemoglobin concentration was "40%" ... representing a hematocrit of about 20% ... and the leukocyte count was 15,250 per cubic millimeter. The red cells were described as follows:

> The shape of the red cells was very irregular, but what especially attracted attention was the large number of thin, elongated sickle shaped and crescent shaped forms.

Herrick's immediate assumption was these were artifacts in preparation, and so he proceeded to carry out a number of investigations to test this hypotheses.

> These were seen in fresh specimens, no matter in what way the blood was spread on the slide. They were also seen in specimens fixed by heat, alcohol and ether, and stained with Ehrlich triacid stain as well as with control stains....They were not seen in blood taken at the same time from other individuals and prepared under exactly similar conditions. They were surely not artifacts, nor were they any form of parasite.... One received the impression that the flattened red discs might, by reason of unusual pliability, be rolled up as it were into a narrow bundle. Once or twice, I saw a corpuscle of ordinary form turn in such a way as to be seen on edge, when its appearance was suggestive of these peculiar forms.[2]

Suspecting that some substance in the plasma might account for the red cell abnormality, he suspended washed red cells diluted in cane sugar solution in a hanging drop preparation, as well as by conventional means. Observing no change in the abnormal cells, Herrick astutely observes: "This ... perhaps suggests more strongly that some unrecognized change in the composition of the corpuscle itself may be the determining factor," an observation that has been amply borne out, now that the structure of hemoglobin S is fully understood.

Treated with rest, nourishing food, syrup of iodide, iron, and thymol, the patient "greatly improved, although there was still to be seen a tendency to the peculiar crescent shape in the red corpuscles." The patient was discharged after a four-week stay. (Managed-care had not yet arrived.) In reporting his patient, Herrick indicated that he did not know the cause for the abnormalities described, and "I report some details that may seem nonessential, thinking that if a similar blood condition is found in some other case, a comparison of clinical conditions may help in solving the problem." With obvious disappointment, he concludes his paper:

> Not even a definite diagnosis can be made.... The question of diagnosis must remain an open one unless reports of other similar cases with the same peculiar blood picture shall clear up this feature.

Early in his career Herrick made what I believe to be his most important contribution to the day-to-day practice of medicine: the recognition of chronic blood loss as a major cause of anemia. As with his observations relating to coronary artery disease, Herrick's attempts to draw the attention of his colleagues to this occurrence was roundly ignored. In a brief paper entitled "Repeated Small Hemorrhages as a Cause of Severe Anemias," he describes the development of anemia from untreated hemorrhoids, observing:

> My attention has been drawn to this subject by having seen five patients with bleeding piles in whom there developed a most grave secondary anemia ... and I am led to write on this topic because in all of these cases for a long time the cause of anemia had been overlooked, and because in three of them, even when the nature of the anemia had been pointed out, there was a disinclination on the part of some to regard so common and so insignificant a condition as bleeding piles as the cause of an anemia so profound and so clearly threatening life.[8]

In four of Herrick's five patients (the last being lost to follow-up), the anemia was corrected after he had persuaded recalcitrant surgeons to treat the hemorrhoids. This led him to conclude:

> Repeated hemorrhages ... may be endured for months or years, the tolerance of the individual to the loss of blood and his power of blood regeneration being sufficient to withstand and make up for the daily drain. But in other instances, the daily loss of small amounts of blood produces the most severe and fatal form of anemia.... The practical lesson to be drawn from these cases is perfectly plain.... It is that severe anemia threatening life and producing a pallor and weakness equal to that of the pernicious variety may at times be caused by repeated

> hemorrhages, often from a condition as easily recognized and easily remedied as hemorrhoids.... The hemorrhage once stopped, recovery, though it may be slow, is complete.[8]

Ever the showman, Herrick relates the following incident. After chiding a group of students for having failed to question a severely anemic patient about hemorrhoids, the following scene ensued:

> Let me show you a picture that you may not soon see again. The patient is willing to give an exhibition though it is embarrassing to him. He will show you what happens nearly every morning.

A large dishpan was brought and the patient squatted down with his back to the class. He was then requested to strain at stool. There emerged from his posterior the largest rosette of piles ever seen, dripping and spurting blood that, with little fecal matter measured several ounces.

> There was a hush until the scene ended. The applause that broke out was more for the patient than for me.

Although Herrick is best remembered by hematologists and cardiologists for his seminal observations (proctologists lay no claim), Herrick always regarded himself as a general physician, resisting recognition as a cardiologist. In a reflection on his early experiences, he writes:

> Though ophthalmology, dermatology, and neurology held out attractions, my leanings were definitely towards internal medicine. For at least 25 years, my aim was to be an all-round practitioner, an internist, as one often says nowadays. In the last two decades, much against my will, there has been forced upon me the term 'heart specialist.'[1]

Modesty was not one of Herrick's virtues. "There was perhaps a little playing to the gallery of students and interns when one made a diagnosis of mitral stenosis by simple palpation that revealed the presystolic thrill and the sharp pulmonary valve closure; or, by noting the collapsing pulse.... one recognized aortic regurgitation." His showmanship was not limited to students and housestaff:

> There was a real pleasure in demonstrating to the attending doctor that his patient was suffering, not from typhoid, but from a malignant type of endocarditis.... The valve was an actively infecting focus.

All this at the bedside.[1]

A student of the classics to the end of his days, Herrick described how he was lured into this interest. At the age of 19, his English teacher struck a deal with the class: anyone who purchased and read all 1,944 pages of the Riverside Edition of the complete works of Chaucer would be exempted for the final examination at the end of the semester. No doubt this crafty scholar had his own methods of determining whether or not the volumes had actually been read. Herrick began an after-dinner address on "Why I read Chaucer at Seventy" as follows:

> The title would more nearly represent the fact if it were changed to "Why I read Chaucer at 69.732 years." Also, the three decimal places might, as in some medical papers, lend an appearance of scientific accuracy not warranted by the content.[9]

Herrick likens reading only the "Canterbury Tales" and nothing more to reading "Hamlet" or "King Lear," without "The Tempest" or "Midsummer Night's Dream." In addition to his 200 medical publications, Herrick presented a number of nonmedical papers on subjects such as "My Summers in a Garden" and "The Story of a Good Boy" at the Chicago Literary Club. His fierce defense of the importance of clinical medicine in an era of emerging chemistry and imaging is evident in his Frank Billings lecture entitled "The Practitioner of the Future." He truly believed that hard work preceded success:

> It seems almost puerile to speak of hard work as an essential.... Yet over and over again we hear doctors bemoaning their fate while all they are doing is to sit around Micawber-like, waiting for something to turn up. I myself have not known a successful doctor who was not a hard worker.[10]

In the words of his close friend and colleague expressed through the words of Chaucer, "He was a verray parfit Knight."[11]

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Principles of Cooperation in Medical-Legal Matters:
A Foreword

ROBERT S. WALZER M.D., J.D.

THE Connecticut Bar Association and the Connecticut State Medical Society (CSMS) are pleased to present their mutually ratified Principles of Cooperation in Medical-Legal Matters. These principles are aimed at providing important information and standards for achieving understanding, agreement, and cooperative interaction between the attorney and the physician engaged to provide examination, testimony, and/or reports or other consultation in legal proceedings. The two organizations recommend that every attorney and physician contemplating or involved in such interprofessional relationships or activities rely on these principles. We urge you to read these and refer to them whenever they might be relevant to your work.

Although these principles were produced recently, they evolved from earlier versions created by the Hartford County Bar Association and the Hartford County Medical Association, and later, the New Haven County Medical Association and the New Haven County Bar Association. The widespread interest on the part of the two professions throughout the state led to a desire to have a statewide standard. The Medical-Legal Committee (now the Health Law Section) of the CBA created this current document in consultation with the other societies, as well as the CBA's Litigation Section.

An interprofessional committee will be created to follow the experience with these principles and to propose any amendments. The Health Law Section of the CBA will assume responsibility for maintaining this work and fielding any questions that may arise in connection with these principles.

We recognize the important contributions of effort, time, and ideas on the part of certain individuals. My predecessor, Atty. Richard L. Jacobs, fostered and kept the project moving over many years while he chaired the Medical-Legal Committee. John J. Williams, M.D., J.D., provided me with invaluable assistance in rewriting the text and lobbying for passage. The members of the former Medical-Legal Committee, who now are the founding members of the Health Law Section, provided ideas and support all along the way over many years. Dr. Joseph Sadowski, and Atty. Cameron Staples, both of the CSMS, contributed ideas and strategies, while the executive directors of both state associations, Timothy Norbeck and Edward L. Johnson, Jr., supported and advised their respective Medical-Legal Committees. The Health Law Section invites comments and reports of experiences with these principles. (Bob Walzer @ (800) 762-7826)

ROBERT S. WALZER, M.D., J.D., is the current chair and a founding member of the CBA's Health Law Section. He is with the health law section of Robinson & Cole LLP, at the Stamford office.

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Principles of Cooperation in Medical-Legal Matters

By the Connecticut Bar Association and the Connecticut State Medical Society

Contents

Preface 607

I. Introduction and Context 607

II. Confidentiality of Communications and Records of Patient-Client 607

III. Medical Records 608

  A. Requested Records 608

  B. Grounds for Withholding from the Patient 608

  C. Subpoenaed 609

  D. Copying Costs 609

IV. Medical Reports 609

  A. Content; Distinguished from Summary and Records 609

  B. Charges 610

  C. Unpaid Bill 610

V. Court Appearances 610

  A. Physician Fact or Lay Witness and Physician Opinion Witness 610

  B. Voluntary and Generally 611

  C. Pretrial Conferences 611

  D. Subpoenas 611

  E. Professional Respect 611

VI. Fees 611

  A. Court or Deposition Time 612

  B. Lawyer's Responsibility for Payment 612

  C. Patient's Responsibility for Payment 612

VII. Canceled Appointments 612

VIII. Lawyer to Notify Physician of Withdrawal from Case 613

IX. Lawyer to Notify Physician of Outcome of Case 613

X. Workers' Compensation Cases 613

XI. Disagreement Between Physicians and Attorneys 614

XII. In Conclusion 614

Preface

The Principles of Cooperation in Medical-Legal Matters was originally created and jointly copyrighted by the New Haven County Medical Association (NHCMA) and the New Haven County Bar Association (NHCBA) as the "Principles for Cooperation in Medical-Legal Matters." That document served as the basis of the present publication, and any text taken from the earlier effort is reprinted with permission and encouragement of both organizations in a continuing cooperative spirit. These two organizations acknowledge their debt to the Hartford County Medical Association and the Hartford County Bar Association insofar as the document's lineage can be traced to their pamphlet, "Principles of Cooperation." Notice has also been taken of a derivative version of Principles published by the Fairfield County Medical Association in 1993.

The Medical-Legal Committees of both the Connecticut Bar Association and the Connecticut State Medical Society, in furtherance of the previous efforts and responding to the need for further clarification and updating, have shared in the revisions that culminated in the present document. The innumerable hours expended over the course of several years by the members of these committees in producing the present version represent their faith and the hope of all concerned that this effort will be fruitful.

Disclaimer: These Principles do not constitute legal advice. A prudent physician would confer with personal counsel regarding any matter of a legal nature.

I. Introduction and Context

1.1 The medical and legal professions exist to serve people. People need physicians and lawyers. Physicians and lawyers should strive to interact with each other efficiently and professionally for the benefit of people involved in medical-legal situations.

1.2 It is our purpose in promulgating these Principles to foster cooperation between physicians and lawyers. Our intention is to make the relationships more productive to help the public which we both serve. We earnestly desire to foster comity and increased cooperation between the professions, the hallmark of which must be mutual respect and consideration, and understanding of the demands of the other's responsibilities and obligations. We are acutely aware this is a "two-way street" and we have attempted to achieve balance and fairness. Where it seemed appropriate, we have tried to explain very briefly both professions' ethical and legal responsibilities.

1.3 These Principles form a framework for interaction between physicians and attorneys throughout Connecticut. They are provided here not to establish any single standard of conduct or method of cooperation between the professions, but to describe how physicians and lawyers with experience in medical-legal matters have found it useful to interact to the benefit of the people they serve. Of course, these Principles do not create legal duties, although much of the content derives from law and ethics. The Principles are set forth as guidelines, created jointly by the various medical and bar associations in Connecticut better to serve the public.

1.4 Since physicians and lawyers interact with each other professionally, the Principles should be implemented by committees of the state, county, or local medical and bar associations, working together in joint session. Therefore, medical and legal associations should look to development of standing interprofessional committees.

II. Confidentiality of Communications and Records of Patient-Client

2.1 The ethical rules of the Superior Court generally prohibit an attorney from disclosing, without the client's consent, information relating to representation of that client. (Rule 1.6)

2.2 Confidentiality: a physician is barred by Connecticut General Statutes (C.G.S.) §§ 52-146o, 52-146e and 52-146d from disclosing communications made to that physician by a patient, the patient's guardian or conservator, unless the patient or the patient's representative explicitly consents to the disclosure, preferably in writing, or an exception applies, as described in paragraph 2.3. (See discussion of "privilege," which is distinguished from confidentiality, in Section III C, Medical Records—Subpoenaed.)

2.3 There are some situations, covered by explicit statute, where a patient's consent is *not* required for the physician to disclose confidential medical information; these include but are not limited to:

(a) when child abuse, abuse of elderly, mentally retarded, physically disabled, or incompetent individuals is known or in good faith suspected, *eg,* C.G.S. §§ 17a-101(b);

(b) when claims are made against the physician, or when there is a reasonable belief that such a claim may be made, disclosure of confidential information can be made to the physician's attorney, liability insurer or its agent, for purposes of defending the action (C.G.S. §§ 52-146c(2));

(c) when a psychiatrist determines that the patient presents a substantial risk of imminent physical injury to self or others (C.G.S. §§ 52-146f(2)); and

(d) when the rules of court, statutes or regulations otherwise permit such disclosure, as apply, e.g., to the Department of Public Health under Public Act 96-47 and C.G.S. §§ 52 -146o(b), and a number of communicable diseases, certain injuries, physician impairment and so on.

III. MEDICAL RECORDS

A. Requested Records

3.1 Upon receiving proper written authorization or court order, a physician should, in compliance with the ethics code of the American Medical Association and American College of Surgeons, furnish to the person authorized, a copy of the patient's medical record. (A subpoena is not the same as a court order; see Section III C.) Section 19a-14-40 of the Regulations of the Connecticut State Agencies (R.C.S.A.) defines the medical record as follows:

> *Medical records, definition, purpose.*—The purpose of a medical record is to provide a vehicle for: documenting actions taken in patient management; documenting patient progress; providing meaningful medical information to other practitioners should the patient transfer to a new provider or should the provider be unavailable for some reason. A medical record shall include, but not be limited to, information sufficient to justify any diagnosis and treatment rendered, dates of treatment, actions taken by nonlicensed persons when ordered or authorized by the provider; doctors' orders, nurses' notes and charts, birth certificate worksheets, and any other diagnostic data or documents specified in the rules and regulations. All entries must be signed by the person responsible for them.

There is nothing in this regulation clearly to indicate that the records or reports of previous treating physicians or facilities, when received by a treating physician, become part of the recipient treating physician's records. It is not settled law that prior records received by a current physician become incorporated with the latter's records. A prudent physician, in deciding a response to a request or subpoena, would check with counsel regarding current law.

3.1(a) If, in accordance, for instance, with R.C.S.A. §§ 19a-14-13, a physician, at the patient's request, had transferred records to a subsequent provider, the earlier physician might wish to retain a copied set (if not the original), but the later provider, as the new primary provider, would retain the complete records.

3.2 A straightforward summary based on the clinical record and/or treatment relationship is seen as part of the above-described case records, *unless* it is created and filed privately as part of the physician's personal notes and observations. Personal records are not part of the medical record. Therefore, certain of the physician's conjectural considerations may be recorded separately in personal files and may be considered distinct from the medical records. Although we are aware that almost all correspondence regarding a patient tends to be placed in the clinical file, it, nevertheless, generally might be prudent to file separately papers which do not fall under the statutory definition of "medical records," such as physician-attorney correspondence, the physician's personal notes and certain other information. The regulation quoted above addresses clinical records only. In the uncommon instance when information not contained in the medical record may be sought by a patient or third party, a prudent physician would seek advice of counsel. Psychiatrists may have other statutory obligations regarding disclosures, for which consultation with counsel would be advisable.

B. Medical Records—Grounds for Withholding from the Patient

3.3 Physicians may withhold a patient's medical record despite request by the patient or an authorized agent, even if the patient or attorney has supplied a valid and an appropriately completed authorization for releasing it, when:

(a) a physician makes a reasonable determination that information in the medical record would be "detrimental to the physical or mental health of the patient" (C.G.S. §§ 20-7c (c));

(b) a physician makes a reasonable determination that the information in the medical record "is likely to cause the patient to harm himself or another" (C.G.S. §§ 20-7c(c)); or

(c) information in the medical record relates "to any psychiatric or psychological problems or conditions" (C.G.S. §§ 20-7c(d)).

3.4 C.G.S. §§ 20-7c(c) provides that the "information may be supplied to an appropriate third party or to another" health-care provider who in turn may consider the circumstances and "release the information to the patient." However, since transmission of such information may have far-reaching legal ramifications, certain information arguably may be withheld either to protect the patient's health or progress in treatment (particularly psychiatric treatment) or to comply with statutory requirements (as in HIV/AIDS or alcohol or drug abuse or addiction). The physician's counsel may feel it prudent to indicate that material is being withheld under statutory authority. C.G.S. §§ 20-7c(c) further provides that "if disclosure ... is refused by the [health-care] provider under this subsection, any person aggrieved thereby may, within thirty days of such refusal, petition the superior court" to require the disclosure. The court, in a privileged or *in camera* review, will then also determine whether the material would be harmful to the patient as above specified and, if the court disagrees with such reasoning, it may order a disclosure.

3.5 A lawyer is responsible for providing a physician with proper written authorization when requesting information about a patient. *A physician should obtain proper written authorization from the patient or patient's representative before divulging any information to a lawyer or other third party.* A physician reasonably may make a determination of the patient's competence to render an informed consent in this matter. The physician also may prefer to rely upon his or her own informed consent release form, and this preference should be respected by the lawyer.

3.6 C.G.S. §§ 52-146i provides that all confidential medical records or written communications to another party should bear this statement:

The confidentiality of this record is required under Chapter 899 of the Connecticut General Statutes. This material shall not be transmitted to anyone without written consent or other authorization as provided [in these statutes].

C. Medical Records—Subpoenaed

3.7 A subpoena, *duces tecum*, requires the physician to appear at the trial, hearing, or deposition with the subpoenaed items. Note that a subpoena, even when signed by an officer or commissioner of the court, is not a court order; all attorneys have such title. When a patient's medical records are validly subpoenaed from a physician upon the written authorization of the patient, the physician is required to produce, but not necessarily disclose the contents or yield the original records in court to the attorneys, at a hearing, or at a deposition. (See paragraphs 2.2 and 3.2 herein.) If, in the physician's best judgment, disclosure of certain privileged and confidential information as contained in the record is considered potentially harmful to the patient, consultation with personal counsel prior to such disclosure is advisable.

3.8 Note that receipt of a subpoena does not authorize the physician to confer with or provide reports to the lawyer who issued the subpoena. It merely requires records production at the appointed time and place. Whether the contents are privileged from disclosure in court or the proceeding may have to be decided by the court.

3.9 "Privilege" is legal protection against being forced to break the expectation of confidentiality governing communications within certain protected relationships. C.G.S. §§ 52-146o comprehensively prohibits unconsented disclosure of any communication by a patient or a patient's conservator or guardian regarding "actual or supposed physical or mental disease or disorder" or information obtained through personal examination by a physician in any "civil action or proceeding preliminary thereto or in any probate, legislative, or administrative proceeding."

3.10 Not all subpoenas are equal. Privileged medical information is statutorily barred from disclosure despite the subpoena, but a judge's signed order may override the statute and require a disclosure. Such instance arises in matters of public safety, for example. If a physician has any concern about the validity of a subpoena or the privilege applicable to the information, the patient's waiver of privilege, or other aspects of the disclosure, the issue should be clarified with personal counsel and/or the patient (if the physician is not a likely defendant).

3.11 Without valid authorization for disclosure, the physician can explain that fact to the court, or present to the court any reasons for not disclosing the records (*eg*, lack of proper consent, records of federally supported substance abuse treatment, emotional harmfulness, public interest in confidentiality, etc.).

3.12 The physician may choose to notify the patient when a subpoena has been received from a party opposing the patient. The purpose of such notification would be to assure the patient that the physician is not willfully violating the trust inherent in a physician-patient relationship. Receipt of a subpoena does not require the physician to provide the lawyer issuing it with a copy of the subpoenaed items, or to show them to the lawyer in advance of the time that the physician testifies.

D. Medical Records— Copying Costs

3.13 C.G.S. §§ 20-7c(b), referring to physicians, states:

No provider shall charge more than forty-five cents per page and the cost of first-class postage, if applicable, for furnishing a health record pursuant to this subsection, except such provider may charge a patient the amount necessary to cover the cost of materials for furnishing a copy of an x-ray....

(No charge may be made if the request is made in support of a Social Security claim.)

3.14 The term "health record" appears to be used by the legislature synonymously with the term "medical" or "clinical record."

3.15 Hospitals are entitled to charge sixty-five cents per page pursuant to C.G.S. 19a-490b(a).

3.16 An attorney should not charge the patient-client an amount that exceeds the cost of obtaining the medical record from the physician.

IV. MEDICAL REPORTS

A. Medical Reports—Content

4.1 Upon receiving a written request for a report accompanied by proper written authorization, a physician should prepare a medical report for the lawyer requesting it. "Medical reports" are distinguished from "records" and, usually, from "summaries," and ordinarily, therefore, are not included in the medical record.

4.2 A "medical report" is a synthesis or explanation of the case made for an attorney or other third party. It is drawn from the records for purposes extrinsic to the clinical care of the patient.

4.3 A "clinical summary" generally is a digest statement of the clinical course, with diagnosis and treatment specifics comparable to a discharge summary. It is usually prepared for the purpose of use in the record. Such a summary is part of the medical record and may be prepared from time to time either absent any request or upon request of patient or attorney. An attorney should not rely on a "summary" as a mini-record. Of course, the request for a summary from a physician in order to avoid the physician's fee for preparation of a medical report is unethical; it may be a disservice to the client. These documents are intended for different purposes and may contain certain data or material in one document but not the other, to the detriment of the attorney and the client. Attorneys should be mindful in making requests for medical information to be specific and narrowly focused.

4.4 Physicians should recognize that attorneys need to receive medical reports in a timely manner, sometimes urgently. Attorneys should recognize that physicians have as their primary responsibility the care of their patients and that it is sometimes difficult to furnish medical reports promptly. When an attorney needs a report by a date certain, the time should be stated in the lawyer's request and the physician should honor this request if reasonably possible, or contact the attorney to make other arrangements. An attorney's courteous and reasonable request should provide at least thirty days' notice for delivery of requested information. Courtesy dictates that the physician should respond within thirty days or promptly notify the lawyer of a delay and provide a reasonable estimate of when the medical report will be sent. Physicians should recognize that attorneys often are under constraint of a court-imposed or a statutory schedule. The attorney should be clear about the information needed and dates, which would aid the physician to understand the time constraints imposed on the attorney and dispel the aura of arbitrariness of the request. A telephone call always helps. Naturally, if the attorney, through some neglect of adequate calendar practice, has missed the time frame allotted and the court denies further time extension, then special arrangements must be made with the physician, who must be appropriately compensated.

B. Medical Reports—Charges

4.5 The fee charged for producing a medical report is determined by the physician. The fee should be reasonable, based on the time and expertise of the physician and the expense involved in preparing and providing the report. A reasonable estimate of the approximate cost of the report should be sought by the lawyer and provided by the physician before the report is prepared, in order to avoid after-the-fact misunderstandings.

4.6 The attorney is directly responsible for payment for a medical report and should make payment in advance, if requested, or no more than thirty days after receipt of the report. The treating physician should understand, however, that the fee for a medical report ultimately will be paid by the lawyer's client, who is usually the physician's patient. The attorney, likewise, should be mindful of this cost in requesting information. Whenever possible, the lawyer should timely direct payment as agreed upon or reasonably requested.

4.7 If it is acceptable to the physician, the attorney may issue a personal "letter of protection" to the treating physician to assure payment for an interpretive report and/or for testimony. When an attorney seeks reports, opinions, or summaries, the physician should understand that the attorney assumes the risk for ultimate payment for the interpretive report for which a letter of protection had been issued, if the attorney's client's lawsuit is unsuccessful. Of course, if the lawsuit is successful, the attorney's client is responsible for all expenses.

4.7(a) The physician's patient, not the attorney, is always responsible for the medical treatment bills. If the attorney and the client/patient agreed, as evidenced, for example, by a letter of protection signed by both of these parties, the lawyer could be authorized and responsible to pay for the agreed upon treatment from sums recovered in the action.

C. Medical Reports—Unpaid Bill

4.8 C.G.S. §§ 20-7 requires that a physician shall provide to a patient upon request complete and current information possessed by that provider concerning diagnosis, treatment, and prognosis. There is no provision for withholding records from the patient because of an unpaid bill. Generally, this is read to refer to medical records, not to reports. However, current *Opinions of the Council of Ethical and Judicial Affairs of the American Medical Association 1992* (§ 7.02) states that "[M]edical reports should not be withheld because of an unpaid bill for medical services." The physician may require payment in advance for a medical report which the physician prepares and provides. (Reports are distinguished from records, as noted earlier in Section IV.)

V. COURT APPEARANCES

A. Court Appearances—Physician Fact or Lay Witness and Physician Opinion Witness

5.1 A physician witness giving testimony in court or at a deposition is entitled to charge for medical-legal services on a time input basis.

5.2 A physician acts as a fact witness, generally, by confining his or her testimony to the facts of an examination or the facts in a record, *eg*, "My examination found a hernia," or, *eg*, "The record states that the patient fell out of bed at 10 P.M." The function of the fact witness does not include an opinion with respect to the hernia or the fall.

5.3 A physician may be considered a "lay" witness in the event his or her testimony concerns some nonclinical event. There, the fact that the witness is a physician is purely incidental. If the questioning changes to a medical inquiry, then the witness's status can change and he or she becomes an expert witness under certain circumstances.

5.4 An expert-opinion witness has the job of synthesizing the case and stating his or her best medical judgment and opinion regarding the case.

5.5 The attorney questioning a physician who is testifying without specific designation as a fact witness or as an expert opinion witness should take care regarding a change in the line of questions from that agreed upon initially. If questions change orientation from a factual line not requiring medical opinion or judgment to one which requires the physician to apply medical expertise or to make medical conclusions, the questioning then transforms the role of the physician from that of "fact" witness to that of "expert" witness, for which the allowable basis of charges for medical-legal service changes.

B. Court Appearances—Voluntary and Generally

5.6 Physicians should recognize that the scheduling of their appearances in court is subject to circumstances over which lawyers often have little or no control. These include the sometimes unpredictable course of a case, the judge, and opposing counsel.

5.7 Attorneys should make every reasonable effort to give physicians as much advance notice as possible and to take into account physicians' schedules. Physicians should be notified promptly when a court appearance turns out to be unnecessary or is postponed (see Canceled Appointments, Section VII). Barring medical emergencies, physicians should make reasonable efforts to be available to testify when they are needed. C.G.S. 52-149a(a) permits a physician's deposition as an expert witness to be placed in evidence in a civil action, a Workers' Compensation case or a probate hearing. While a physician's physical presence in court as a medical expert usually is necessary, this option to enter the deposition sometimes might obviate the need for that physician's personal appearance. Attorneys are encouraged to explore this option when it offers a feasible convenience.

5.8 If a physician is sought or scheduled for an appearance and the need is canceled, the physician should be notified immediately with an explanation (such as settlement).

C. Court Appearances—Pretrial Conferences

5.9 Being in court is not an everyday or even common experience for most physicians. Lawyers should make every effort to familiarize physicians with relevant court procedure and techniques of direct and cross examination. We strongly recommend a pretrial conference between the physician and attorney to discuss courtroom procedure, and to review the patient's medical record.

5.10 Physicians should keep in mind the defined role for which they have been summoned, and to comport statements accordingly. Usually, physicians are testifying as independent medical experts or medical fact witnesses, expressing themselves to the best of their knowledge about the medical opinions or medical facts, respectively.

D. Court Appearances—Subpoenas

5.11 Court rules do not require a subpoena to be issued for a medical witness, and physicians and attorneys should cooperate whenever possible to avoid the need for a subpoena. Physicians, however, should recognize that a lawyer can be criticized by a court and/or be held legally responsible for the consequences of the failure of a physician to appear in court. When the voluntary appearance of a physician cannot be arranged, court rules allow a lawyer to subpoena the physician and the original medical records of the lawyer's client.

5.12 Lawyers should make every attempt, when issuing a subpoena, to provide sufficient advance notice to a physician of the date and time of the required appearance, making every effort to minimize disruption of the physician's scheduling of patients. We do not condone a lawyer's misuse of a subpoena to compensate for failure to timely notify the physician and make provision for pretrial discussion.

E. Court Appearances—Professional Respect

5.13 In court, physicians and attorneys should recognize that they serve as models of their respective professions and should comport themselves honorably and with mutual courtesy and respect. Physicians, particularly those unfamiliar with the court, are often surprised and some are offended by the adversarial method that is the foundation of our legal system. Attorneys should keep in mind that the adversarial method is foreign to many physicians trained in scientific inquiry. Physicians need to understand that lawyers must be zealous advocates when they present their clients' cases, knowing that the trial may be the one opportunity the client will have to receive fair compensation for the injuries sustained.

5.14 The touchstones for both professions must be a sense of service to the person who is relying on both the physician and the attorney, mutual respect for each other's profession, mutual consideration of their circumstances and needs, and mutual courtesy.

VI. FEES

A. Fees—Court or Deposition Time

6.1 The fee charged for medical-legal services is determined by the physician. A physician is entitled to charge for serving as an expert medical witness even if the physician has been issued a subpoena. The lawyer who issued the subpoena is responsible for paying the physician. Physicians are not paid for a medical opinion. Physicians' medical opinions are not for sale.

6.2 The attorney should be open and receptive to a physician's requirement for advance compensation for time contracted to be spent in evaluating a case or for time spent on the stand or otherwise away from his or her medical practice, as for example, in travel.

6.3 If a physician has been given a certain date for a scheduled appearance as a fact witness or an expert witness for the defense, and the physician has canceled either office hours or surgery time in order to appear, and the appearance is canceled by action of an attorney or the court, the physician is entitled to charge for the economic loss suffered from the lost practice time.

B. Fees—Lawyer's Responsibility for Payment

6.4 Regardless of the outcome of litigation, or of the ability of a patient-client to pay, an attorney must accept responsibility for payment of the medical-legal services a physician provides as an expert or a fact witness at the request of the attorney. The attorney shall make the appropriate arrangements with the client for the physician's payment. The attorney should obtain the patient-client's authorization to pay the physician directly out of the future settlement, judgment, or arbitration award proceeds. But, if the plaintiff's case should be unsuccessful, the attorney is nevertheless responsible for paying the physician for services contracted. However, an attorney is not liable for the payment of a client's bills for medical treatment. Questions regarding a physician's charges should be settled before the physician undertakes the responsibility.

6.5 Medical-legal services include, but are not limited to: reports, time spent testifying, physician-attorney conferences, case preparation, requested medical examinations, case evaluations, and review of medical records.

C. Fees—Patient's Responsibility for Payment

6.6 Physicians who treat patients involved in personal injury cases are free to collect their fees for medical services from their patients prior to the conclusion of litigation. (Note: Workers' Compensation cases may require physicians to await payment of fees for medical services until the case has been adjudicated. See Workers' Compensation, Section X.) An attorney should not advise a client to refrain from, or to delay paying, a physician's bill.

6.7 Nonetheless, when a patient-client cannot pay a physician's fee for medical services for an injury, lawyers should make every effort to provide for payment of a bill from the proceeds of insurance or other benefits. To avoid problems in obtaining a patient-client's assignment of benefits (except in Workers' Compensation cases, where the assignment of benefits is prohibited), lawyers should incorporate provisions for assignment of benefits into the client's retainer agreement at the time the attorney-client engagement is executed.

6.8 When a patient-client cannot pay a treating physician's fee for medical services for an injury, the physician should consider foregoing formal action to collect the fee in a spirit of cooperation and comity until circumstances are clarified. The attorney should notify the physician in writing and in a timely manner that the physician's fees will be protected in the event proceeds are available from a settlement, judgment, and/or insurance coverage.

6.9 A plaintiff's attorney should not represent to the defense and/or to the court that a physician's fee is reasonable and later contest the fee. If an attorney presents a physician's bill in court or uses it in settlement negotiations, and an award or settlement is based on the full and uncontested amount of the bill, the attorney should not, at a later date, then challenge the bill. This is unethical and may be construed as fraud.

VII. CANCELED APPOINTMENTS

7.1 Lawyers should make every reasonable effort to minimize disruptions in physicians' appointment schedules. Externally imposed exigencies will often make it difficult for the best intentioned lawyer to adhere to a strict schedule. Physicians and attorneys should work together to minimize cancellations.

7.2 When lawyers have given sufficient notice for physicians to make reasonable efforts to resume their normal schedules, physicians should not charge for the cancellations. One approach physicians' offices have used successfully is to notify patients that if the court appearance is canceled for any reason, the physician will try to furnish enough notice to the patient to permit the original appointment to be kept.

7.3 Before medical-legal services are furnished, the physician and attorney should address, preferably in writing, the physician's policy regarding charges, if any, for missed and canceled appointments and court appearances, in order to prevent misunderstandings. The attorney should be responsible for reasonable charges for such dates scheduled at the lawyer's request and which are missed or canceled without adequate notice to the physician and where the physician is unable to reschedule that time gainfully. (See Section VI, Fees.) In instances in which an advance retainer agreement is made, the physician would provide for return of the advance payment, withholding any sums only in accordance with that agreement for missed appointments or cancellation the same day or within one to three days of the scheduled date.

VIII. LAWYER TO NOTIFY PHYSICIAN OF WITHDRAWAL FROM CASE

8.1 When a lawyer withdraws from a case, the lawyer should notify the treating physician within a reasonable time. Such notification lets the treating physician know that this attorney will not continue to use the physician's services. Furthermore, if the treating physician has agreed to postpone the collection of an outstanding bill for medical services, the attorney's notice of withdrawal also provides notification that he or she will not be able to help to get the bill paid. But, keep in mind, if the attorney has requested or contracted with a physician to act as an expert or a fact witness, the withdrawing or retiring attorney continues to have responsibility to remunerate the physicians he or she has hired to the extent of the work already done, unless the new attorney assumes the responsibility in writing and communicates this protection to the physician.

IX. LAWYER TO NOTIFY PHYSICIAN OF OUTCOME OF CASE

9.1 As a courtesy to a physician who has participated in a case that comes to court, the lawyer should notify the physician of the outcome of the case. A physician's involvement in a medical-legal case is often a learning experience; being informed of the outcome is an aid to evaluating the experience and it brings the matter to a closure.

X. WORKERS' COMPENSATION CASES

10.1 The fees of physicians and attorneys in Workers' Compensation cases are subject to review and regulation by the Board of Workers' Compensation Commissioners. Injured workers' medical bills are paid by an employer's insurance company (or by the employer when the company is self-insured). Former C.G.S. §§ 31-305 was repealed in 1995; certain duties of attending physicians and their fees are now covered in §§ 31-279-9 of the Regulations of Connecticut State Agencies. (The current Bulletin No. 41, issued by the Workers' Compensation Commission, containing this and other regulations as well as the entire Workers' Compensation Act (Title 31) and other pertinent information, is available free of charge at any State of Connecticut Workers' Compensation Office.)

10.2 Although an injured employee's employer or its insurer pays the employee's medical bills, the obligations of the treating physician are to remain with the employee, as in any other physician-patient relationship. Under R.C.S.A. §§ 31-279-9, treating and consulting physicians are required to adhere to certain procedure and protocol, some aspects of which are detailed in the following paragraphs.

(a The employer or its insurance carrier will receive an early original report of injury, and such regular subsequent progress reports from the attending physician as may be reasonably required in each case.

(b) No fee will be charged by the attending physician for the completion of any of the forms approved by the Board of Compensation Commissioners or for routine progress reports submitted. Where detailed reports are requested or indicated, requiring a significant expenditure of time by the attending physician, a reasonable additional charge for such time will be appropriate.

(c) It is the duty of the attending physician, without special request, to keep the employer or insurance carrier advised of any significant development in the course of his or her treatment, such as the attainment of maximum medical improvement, a hospital admission, a surgical procedure, a failure to accept indicated treatment or to keep scheduled appointments, or an ability to return to gainful employment.

(d) Upon reasonable notice, an attending physician will be available as a witness in hearings before a compensation commissioner, for which appearance payment is allowed. The physician is to be paid a reasonable fee by the party requesting his or her attendance, subject to any pertinent provisions of law.

(e) All charges for medical, surgical, hospital, and nursing services, except those for expert or fact testimony, shall be solely the responsibility of the employer or carrier, and no claim will be made against the injured employee for all or part of a fee.

(f) It is improper for a physician to refuse to send out the patient's medical report to a party properly entitled thereto only because the medical bill for services rendered still has not been paid.

(g) Violation of these regulations shall constitute sufficient cause for a removal from the approved list of physicians maintained by the board of compensation commissioners.

10.3 In addition, R.C.S.A. §§ 31-279-9 provides that:

> Each medical report concerning any injury of an employee sustained in the course of his or her employment shall be furnished within a reasonable time after the completion of that report, but not more than thirty days after its completion, at the same time and in the same manner, to the employer and the employee. If the employee is represented by a lawyer, each medical report shall be furnished to the lawyer instead of the employee.

10.4 A physician generally should not charge more than once for the cost of preparing the same medical report. Attorneys should recognize that a report is not part of an examination nor is it included in the charge for an examination, unless so contracted by the attorney with an examining witness of fact or expert-opinion witness. As stated above, the medical report is distinct from the medical summary and medical record (see Section IV, Medical Reports). Since medical reports are not part of the medical record, the charge for providing copies should not be governed by C.G.S. 20-7c(b) and 19a-490b (see Medical Records - Copying Costs, Section III).

XI. DISAGREEMENT BETWEEN PHYSICIANS AND ATTORNEYS

11.1 There will be occasions when physicians and attorneys disagree about medical-legal issues. In these instances, we encourage the attorneys and physicians to try to resolve their differences as professionals, keeping in mind their differences should not be harmful to the best interests of the patient-client. If the disagreement cannot be resolved on a personal level, medical-legal liaison committees are available to mediate medical-legal disputes. Such mediation is strictly voluntary.

11.2 Interested physicians and attorneys should contact the county or state medical association for information about the liaison committee available to the parties. In the event that an aggrieved party finds it necessary, inquiry may be made or a complaint may be filed with the state or county professional association or the Statewide Grievance Committee of the state bar (comparable to the state board of medical examiners).

XII. IN CONCLUSION

12.1 We believe the Principles of Cooperation in Medical-Legal Matters presented here will make it easier for the members of our professions to cooperate with each other in a spirit of mutual respect and goodwill for the benefit of those we serve.

12.2 Nothing herein is to be considered or construed to be legal advice for any particular case. Each case differs, and professional conduct is ultimately the responsibility of the particular attorney or physician. In the event of any question regarding conduct in medical-legal or other professional matters, consultation with personal counsel is a prudent measure. These Principles are guidelines for interprofessional relations and general information, and while they refer to certain statutes and regulations, they are not legal advice.

12.3 There is, in our opinion, a tendency to use sample or generic forms and letters with the mistaken view that we recommend them for use in lieu of appropriate or necessary legal advice and without suitable adaptation to the situation, possibly leading to unfortunate circumstances. We have, therefore, decided not to provide sample forms as were provided with previously published Principles.

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◆ The **PHP** recognizes that most people may not know what to do when they suspect that a physician may be impaired, or how to help him.

◆ Referrals are accepted and come from many sources including colleagues, patients or friends, family members, and often from the affected physicians themselves.

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Commentaries

The Primary Care Physician and Managed Care

> "Life is short, the art long, opportunity fleeting, experience treacherous, judgment difficult."
>
> *Hippocrates*, Aphorisms, Sec.I.

Hippocrates lived in the fee-for-service world, and one wonders what he, the first memorable primary care physician (PCP), would have said about managed care. Many PCPs find their world turned upside down. Overworked, unappreciated, and underpaid for years, internists, pediatricians, and family practitioners find suddenly that the rest of the medical world cannot live without them. These perennial wall flowers now find their dance cards filled with ardent suitors from hospitals, physician management companies (PPMs), specialist-dominated group practices, and assorted lawyers and consultants.

It's flattering, and many of the suitors wave cash around, income guarantees, and stock options. But, it's also confusing, and one wonders what to do. After working with a large primary- care group for several years and talking to many other primary-care groups around the state, this observer would suggest that a prudent PCP examine his options very carefully before selling his future career. It may be a once-in-a-lifetime opportunity, but the trick is to pick the right opportunity.

How Much Is a PCP Worth?

No one wants to think of himself as a commodity, but physician practices have been valued and sold for years. Many consultants pick the one-time gross revenue number. This old standby is meaningless in the managed-care world, if indeed it ever made sense. PCPs in Connecticut have sold their practices for amounts ranging from $150,000 to $500,000 during the past few years.

Why is anyone willing to pay this amount to purchase a practice? The average Connecticut PCP works 50 to 60 hours a week, has an overhead of over 50%, and takes home $120,000 to $175,000 a year. Even the most efficient PPM probably can't cut the practice overhead by more than 10% or 15%. Some PPMs think they can increase practice revenues by bringing more patients in the door. That may work in competitive markets, but most established Connecticut PCPs are already close to maximum capacity. Moreover, those who buy practices will admit that in many cases the "nine to five" mentality kicks in as soon as a doctor sells his practice. Often, newly salaried doctors don't want to work hard when they have a steady paycheck. Thus patient revenues actually decline rather than increase after a practice sale. Moreover, the PPM's profit margin is further eroded by central corporate expenses to support the practice. In the end, most PPMs make less than 5% profit a year on each purchased practice.

But the buyer of primary-care practices doesn't care much about the profitability of your practice. Hospital buyers care about filling their beds and their ancillary facilities with your patients and PPM buyers care about the "managed-care arbitrage."

The managed-care arbitrage, an old concept in California, is new to the Northeast. In the indemnity insurance world the average PCP's patients spend about $4 million per year on health care, minus 15% for administration, or about $3.5 million per year on medical expenses. For example, a hypothetical internist in the fee-for-service indemnity world has 1,000 commercial and 500 Medicare patients in her practice, is grossing $400,000 with a 60% overhead, and takes home $160,000 per year. The average commercial insurance premium is about $150 per member per month (pmpm), and the average sex and age adjusted Medicare expenditure is about $450 pmpm. The total health-care expenses for this practice is 1.8 million dollars for commercial and 2.5 million dollars for Medicare patients. The health-care dollar is spent as follows:

Administration and profit	15%	$675,000
Hospital	40%	$1,800,000
Specialists	20%	$900,000
PCPs	10%	$450,000
Pharmacy	10%	$450,000
Ancillary services	5%	$225,000
Total health-care expenses		$4,500,000
Total medical expenses		$3,825,000

When this hypothetical practice switches to a managed-care gatekeeper system, it becomes more efficient as the "fat" is squeezed out. The commercial premium may drop to $120 pmpm and the Medicare premium to $425 pmpm. But the distribution of the health-care dollar changes. Hospital bed days fall 30% to 50% and aggregate specialist reimbursement falls about the same percentage. The primary-care share remains constant or increases as PCPs perform services previously done by specialists. The PCP is now the gatekeeper and controls the flow of dollars into the whole system. She controls a different budget for the same 1,500 patients:

Administration	15%	$600,000
Hospital	25%	$1,000,000
Specialists	12.5%	$500,000
PCPs	12.5%	$500,000
Pharmacy	10%	$400,000
Ancillary	5%	$200,000
Total health-care expenses		$3,200,000
Total medical expenses		$2,600,000
Total premium collected		$4,000,000

Managed-Care Arbitrage
$800,000 (Premium—Health-Care Expenses)

Note carefully the result of a PCP gatekeeper managed-care system. The medical premium drops, the hospitals and specialists make less, and the PCPs make a little more. But, more importantly, four million dollars are collected in medical premiums and only 3.2 million dollars are spent on health care, including administration. The difference is called the managed-care arbitrage, and it goes to whomever controls the flow of health-care dollars, that is, to whomever controls the PCPs.

Of course, a practice will not change overnight from indemnity to managed care, but over time a significant percentage of most primary-care practices will be managed care, and the opportunity to arbitrage the utilization efficiencies will exist in a parallel percentage.

We now see the true value of a PCP, as her practice changes from indemnity to managed-care patients, there is profit to be made from the fat that is squeezed out of the system. Currently, Connecticut managed-care companies enjoy most of the profit of the arbitrage. Some are willing to split it with primary-care groups, others give small incentives of a few dollars pmpm under a primary-care capitation formula that rewards doctors for favorable utilization profiles, while keeping the lion's share of the profit for the HMO.

Hospitals want something different from a primary-care practice. They want control of the 2.6 million dollars spent on health care. They want those dollars going to their hospital and its outpatient ancillary facilities.

Are you getting a good deal when you sell your practice for $300,000 or $500,000? Some PCPs might say that being a gatekeeper is a lot of extra work and that since managed care is here to stay for at least a decade they deserve a piece of the managed-care arbitrage as fair compensation. That appears reasonable. How should you position yourself for managed care? Let us examine the options.

1) Avoid it.—*I didn't become a doctor to worry about how much everything costs. It is distasteful and I will avoid the whole thing and see only indemnity insured patients.*

Good luck. Right now 30% to 40% of Connecticut patients have managed-care contracts. As the government programs turn so will the rest of the industry. In five years fewer than 25% will still have indemnity insurance. If you can fill your office with these patients more power to you. The rest of us must deal with managed care.

2) Go it alone.—*I will practice cost-efficient medicine and pocket the arbitrage profit from my practice.*

You really cannot do it yourself. With only 1,500 patients, you cannot avoid the risk of small numbers. If you could collect the whole health-care dollar for your patients and pay all the bills, you will still lose hundreds of thousands of dollars if one of your patients needs a transplant. You have to pool the risk with a group of like-minded PCPs to cover collectively at least 25,000 patients to avoid the luck of the draw.

3) Sell to a hospital.—*The hospital administrators offer to buy my practice and guarantee my salary and give me nice benefits.*

While this option is popular, it's not without risks. Connecticut hospitals are nonprofit and cannot by law pay more for your practice than the fair market value. The hospital risks its nonprofit status for private inurement if they pay too much. If your practice is not properly valued by an independent appraiser you risk Justice Department fines and federal taxes. A independent appraiser cannot add value to the sale price by factoring in potential referrals of patients to hospital facilities, nor can he factor in the managed-care arbitrage. In addition, one of the Justice Department's current high priority initiatives is the investigation of hospital acquisitions of medical practices. It is highly unlikely, therefore, that you can sell your practice to a hospital for a price you would receive from a private company such as a PPM.

Moreover, a hospital may guarantee your salary, but that is not ironclad security. Just about every hospital in the country is losing money from purchased practices. Pennsylvania's largest nonprofit hospital system, Allegheny Health, Education and Research Foundation, went bankrupt in mid-1998 partly because it could not manage purchased physician practices. This hospital system and some major ones in New York and Boston have begun firing full-time physicians as a cost-saving measure. Some of these doctors have national reputations. Connecticut hospitals have also experienced significant financial losses from purchased practices. The end result of your hospital deal could certainly be a PCP pink slip.

4) Sell to a physician practice company.—*A smooth talking business tycoon offered me a lot for my practice, and I won't have to worry about the hassles of running a business.*

A private or a publicly traded company can pay you whatever they wish for your practice. Typically, the PPM buys all the assets of a practice, and the physicians sign a

30- or 40-year contract to provide medical services. The PPM takes about 15% or 20% of the practice's income for management fees. They may also offer a productivity bonus, profit sharing, and professional management. But, you will then be working for a large company with stock holders, quarterly quotas, and a bottom line profit mentality. If this fits your career goals it might be the best deal for you. There are, however, major risks with this strategy. Most PPMs buy your practice for stock in their publicly traded company. You have to hold the stock for a few years before you can sell it. If the stock price goes down, you lose. FPA, one of the major PPMs, is a good example of this scenario. FPA stock was trading as high as 40 dollars at the end of 1997. If fell to six cents by the summer of 1998 when FPA declared bankruptcy. Those doctors who sold their practices in exchange for FPA stock were very unhappy. Medpartners, formerly the country's largest PPM, went through a similar scenario in 1997. FPA and Medpartners PCPs are now being sold like commodities as those companies scramble to raise cash.

If you sell your practice to a PPM ask for cash not stock! Also, when you consider employment by a PPM think of the long-term picture. There is only so much fat that can be squeezed out of the health-care system. It will become progressively more difficult to keep squeezing without affecting patient care. Sooner or later the managed-care arbitrage will disappear. Wall Street will look for the next hot industry, and PPMs will consolidate and become large utilities. It might not take that long for your practice to be sold to another company. That means it is very likely that sooner or later you will have a new boss in a new company. Do you want to work for faceless managers in a multibillion dollar national company? I don't know how employed doctors who cannot turn a profit will be treated or what pressures will be exerted to use certain new drugs and to practice medicine in a corporate way. Do you?

5) Start an HMO.—*Doctors in the state will band together and start their own HMO which will provide great care, good fee schedules, and stop Wall Street from raping the health-care system.*

There are now about 16 managed-care companies in the state. They will not all survive. It takes money and expertise to run an HMO. Despite recent federal legislation making it easier to start a provider-sponsored HMO, it is not an easy project. A doctor-owned HMO sounds attractive (and familiar), but it won't sweep the state and drive out all the 'evil' nondoctor-owned HMOs. It will still have to compete on the basis of performance. It will still have administrative costs, competitive premiums, and managed-care reimbursement rates. It will not look much different from the average HMO. Moreover, you cannot expect your whole practice to flow through a doctor-friendly, doctor-owned HMO. If you want to start such an organization, good luck, but it won't solve your problems with all the other plans.

5) Join a multispeciality organization.—*I get along well with my specialist colleagues and we can work together to practice cost-effective care.*

The usual scenario is as follows: A group of specialists see the handwriting on the wall and decide that to maintain their referral base they will hire or ask a group of PCPs to join them in a "collegial organization." Multispeciality IPAs were tried in Connecticut in the 1980s. Those that are not heavily weighted towards primary care are now dead. They suffered from all the political problems of PHOs and they didn't even have access to favorable hospital bed day rates. The last of this dying breed is the CSMS-IPA, which represents 7,000 doctors who contract with the MD HealthPlan/PHS monolith. That IPA has been unmanageable and has hemorrhaged money profusely.

Multispecialty group practices are different from IPAs. They have been quite successful in other parts of the country. The Mayo Clinic is a good example. But in the managed-care world you need the right mix, at least 60% primary care and adequate key specialists including cardiology, gastroenterology, oncology, orthopedics, dermatology, and ENT. Some of the groups forming in Connecticut have enough neurosurgeons, pathologists, and ENT doctors for the whole state, combined with only a handful of PCPs. These are not cost-effective managed-care practices. They are political cartels and they will fail. On the other hand, if you can form a well-managed multispecialty group practice with an appropriate mix of PCPs and specialists with a good compensation model you could have the ideal vehicle to prosper in the managed-care arena. It takes a long time and a lot of hard work to form a large group practice. Pick your partners wisely and ask an experienced consultant to help.

6) Join other PCPs in a large group.—*I will join together with other PCPs and directly contract with the HMOs.*

PCPs can come together in a large group practice, an IPA, MSO, LLC, or a similar bargaining entity. This group can then negotiate managed-care contracts, assume the risk and take on the responsibility and rewards for managing their patients' health-care resources. Such a group requires hard work, money, and administrative support. Some have found capital partners with managerial and administrative expertise, while others have raised money internally and purchased help. Ideally, a primary-care group can manage the distribution of the health-care dollar. They can pick and choose specialists and hospitals to work with and they can negotiate fees and hospital rates. Some large primary-care group practices and IPAs have had spectacular success in California, where they have been able to influence the local health-care system and to benefit from the work of managed-care gatekeeping.

Unfortunately, this model has not been entirely successful in Connecticut. While well-managed primary-care IPAs and group practices have formed they have had some difficulty obtaining managed-care contracts. Connecticut hospitals have more bargaining power than do those in California. There are fewer hospital beds per capita in Connecticut and there are usually only one or two hospitals in each geographic area. Thus Connecticut hospitals enjoy monopoly or oligopoly pricing and have been able to keep per diem hospital rates high, almost twice as high as neighboring New York and Massachusetts. Managed-care plans need a competitive hospital rate to be profitable, and the local hospital often has more bargaining power than the local primary care group. Hospitals usually demand an exclusive contract for their physician health organization (PHO) as the price of a competitive per diem rate.

Therefore, while a primary-care group may be the ideal model for managed care, its time has not yet arrived in the state of Connecticut. In some cases PCP groups have been able to form a partnership with the local hospital. Strategically, the rest of Connecticut PCP groups must decide whether to work with the local physician hospital organization, to work with a competing hospital if there is one in town, or to find some other way of getting a contract.

7) Join a hospital organization, a physician hospital organization (PHO).—*I am loyal to the local hospital and my specialists colleagues, and we are all in this together. The hospital and the doctors will bargain together to get the best deal on managed-care contracts.*

Every hospital in Connecticut has started a PHO that includes every doctor on the medical staff. While there is nothing wrong with the concept of a PHO, nationally these organizations have a dismal record. They fail for political reasons. Everyone wants to keep his traditional piece of the health-care pie. Hospitals want to keep the beds full or to receive a flow of the health-care dollars in their ancillary facilities to make up for losses as bed days fall. Specialists want to keep their fees high for specific procedural codes. And a small minority of selfish doctors churn patients and unbundle codes to make up for lower fees. Potential profits evaporate.

This doesn't, however, mean the end of PHOs. One of the advantages of living on the East Coast is that we can learn lessons from West Coast doctors who have been down similar managed-care roads a few years before us. Some of their PHOs have evolved into second and third generation models. In the second generation model, those PCPs who want to work with the system form separate risk pools called "pods" under a general PHO umbrella. These primary-care pods (pool of doctors) pick key specialists to work with, specialists who are willing to practice cost-efficient, quality patient care. If these pods are successful, the system can work quite well. PCP pods and their affiliated specialists can benefit from cost-efficient care. Hospitals benefit from pods, because at least a portion of each managed-care contract is being managed efficiently. Moreover, the doctors solve the hospital's political problems. The PCPs choose which of their peers they wish to work with. The noncompliant doctors are left out in the cold and must learn the system or suffer the financial consequences.

The next step in the evolution of PHOs is the third generation model, in which groups of PCPs and affiliated specialists form a special relationship with the hospital and contract directly with managed-care plans or employers. The primary-care group does its own utilization review and quality assurance and receives some of the administrative portion of the contract to support these programs. This, of course, is getting close to the provider-sponsored network that may or may not be the future of health care. In Minneapolis, another incubator of managed-care models, there are over 20 independent groups of doctors who work with hospitals to bypass insurance companies and contract directly with employers.

While many PCP groups are not attracted to the PHO models as first step, it is a strategy that seems to be working in Connecticut. While it may be a slow process, it does eventually work and it brings the hospitals and the specialists along with the PCPs into a true partnership. It allows the PCPs to capture a group of risk lives to manage under a contract in order to gain experience and a track record, the solid foundations upon which to build a successful organization.

Summary

I have explored the major options open to PCPs. There are multiple variations on these themes. While the Connecticut market is fluid, one thing is clear, the solutions will vary from place to place. Health-care reorganization is a local phenomenon. Individual doctor groups can have a major influence on the direction of their local market. The future is uncertain, but whatever happens in Connecticut it will be evolutionary. PCPs must understand the realities of the current marketplace and plan a strategy to work with those realities to achieve their long-term goals. The choices we make today will have ramifications flowing far into future decades. PCPs and their patients will have to live with the consequences of these decisions. Please choose wisely.

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The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America

A friend of mine recently wisely commented that it would be impossible to socialize anything in the United States of America until and unless you could get the middle class to accept entitlements and to like them. Based upon that, and on the public's obvious penchant for what they have mistakenly believed to be "free" medical care, he predicted that insurance companies will have about 10 years left to make money in managed care. He assumed that by then, these companies would start to lose money and would leave the field. At that point, government would have to step in to fill the void. That would leave us with a "single payer system." In other words, a government owned and controlled, socialized health-care system.

I agree with his model. But I think that his timing is all wrong. His "future" has already passed. The government, by being "too clever by half," has already missed its opportunity to socialize medical care in America. Now that, by itself, is a good thing. But in its long-range zeal to socialize medicine in the United States, the government has grievously damaged the basic fabric and infrastructure of our medical care. And we will all suffer because of this for many years to come.

My friend's "future" really started back with the passage of Medicare in 1965, and continued with the HMO and ERISA acts of 1974. Medicare was, after all, the ultimate "middle-class entitlement." Our current president, Bill Clinton, is merely advancing concepts that Hillary Rodham Clinton, Ira Magaziner, Robert Reich, and others of that ilk were already working on way back in the 1970s. He's the "pretty boy" out front. The "theoreticians" have been working on this, quite successfully, for a long time now. Those "10 good years for the insurance companies" that my friend was looking for have long since passed us by. These companies are well into their loss phase, though many may not yet recognize it as such!

Take a look at the stock charts of most of the managed-care players, such as Oxford, Humana, Columbia-HCA, United Healthcare, Foundation Health Systems, Maxicare, and PHP Healthcare. They are already "the walking dead." Even the charts of the big traditional insurers such as Aetna and Cigna are showing early signs of breakdown. These companies, in turn, represent a microcosm of the entire U.S. economy. The latter is also at risk because we have not had just "managed care," but a managed, government/corporate-cooperative rigged macroeconomy as well. Our economy has been living on borrowed time and funny money. Don't let that total on the bottom line of your stock portfolio fool you. Most of your money has already gone to "money heaven." You just don't know it yet.*

Medically speaking however, there is one very big fly in the ointment. When the economy collapses, there won't be enough tax money to do any of the health-care "fixing" that the social planners have been gleefully looking forward to, single-payer or otherwise. And the physical and personnel resources will no longer be there either. You can forget about that 10-year horizon. Six years from now, maybe even less, there will be too few doctors, too few specialists, and too few hospitals to give modern, decent care. Name the resource, it will be in short supply, or, in some cases, missing entirely. Because of misguided policies, and particularly because of a cynical attitude towards physicians, our government will have bankrupted many physicians and medical facilities, or will otherwise have driven them out of private practice.

Believe it or not physicians are being financially ruined even as we consider these issues. Many do not even know that it's happening to them. They don't realize, for example, that the stock they received from "management companies" in exchange for their practice assets will be worth nothing by the time that they try to sell it. They don't know, or else don't appear to care, that the Oxfords, Aetnas, Cignas that are three to eight months behind on payments to them for services already rendered to patients will never make good on their debts. And most physicians seem to have forgotten that they are forbidden, either by contract or by law, to look to the treated patients for payment!

Some physicians, such as myself, have retired prematurely. We have withdrawn our knowledge and services from the available pool of physicians in this country. We will never be able to return to practice because of the excessive financial considerations attendant upon setting up a practice the way we would like to do it. This is especially true given the general medical-legal and regulatory climate that has been created by government and by the plaintiff's bar. And more physicians will begin to do as I have done. Some will leave by choice, as I did. Others will do it because the cumulative evil effects of past government policies will force them to do it. This will further reduce both the quality and quantity of available health care.

Incidentally I must say that it is very sad to look back on my 24 years in practice and to realize that for all of that time, my government just considered me a cog in a political game of national health-care policy. It distresses me to realize that the same government that would willingly confiscate all of my money through excess taxation, fines, or by any other means at its disposal, would also be perfectly willing to put absolutely no value whatsoever on the services that I rendered, or on the unique gifts that I brought to medical practice. Gifts that I willingly shared with my patients for so many years, with such great joy and satisfaction. And it bothers me that our government thought so little of the medical profession that it created laws such as Kassenbaum- Kennedy which made me, and others like me, virtual criminals every time we billed for our services.

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*This article was submitted for publication 26 August 1998.

In addition to the destruction of our physician infrastructure, many good, decent, and badly needed small hospitals have already been ruined by purchase, closure, or inappropriate mergers. In other cases these valuable community assets, which were built through the charitable contributions of local citizens, have been destroyed by the theft of their patient base by single-service, for-profit outpatient "service stations" that have skimmed off the easy cases and have left the difficult, expensive, and unreimbursed care to the small local hospital. These wonderful, local institutions will not be easily recreated.

Yes, as I see it, the golden age of American medicine has passed, and a new, potentially dark age is descending upon us. And it need not have happened this way. All we had to do was ignore the policy wonks, disregard the theoreticians who were totally ignorant of the real world of medicine, and avoid the planners. All we had to do was recognize the outrageous arrogance of those who claimed that they could "manage health care," and worse, manage the entire economy. We should have been forewarned, and dissuaded by their hubris. And most of all, we shouldn't have believed that word "free" when they used it.

It is really quite sad that the word "free" is so enticing. It has seduced the entire nation. And now we will all have to pay for that seduction. Fortunately, given the nature of human relationships, and our propensity to seek them out for our mutual benefit, it will probably be a relatively easy matter for many patients to reestablish the old-fashioned doctor-patient relationship that traditionally served as the cornerstone of medical care in America. But regaining the personnel and physical resources, the finances, and the professional excellence and infrastructure that have been lost through corporate and government meddling in health affairs will take a longer time. It can be done. With trust in people. And with a wary eye towards government.

But then again, that's just what the founding fathers would have recommended to us.

Stephen R. Katz, M.D.
Fairfield

Dr. Katz practiced obstetrics and gynecology in Fairfield from 1971 to 1994. Since then, he has been a consultant, writer, and speaker on health-care policy and legislation. Dr. Katz is the president-elect of the Connecticut State Medical Society, and a member of its Committee on Ethical and Judicial Affairs. He is also a member of the Board of Trustees of the Fairfield County Medical Association. More of his views on health care policy can be seen on the Internet at http://pages.prodigy.com/DOCTORINFORM)

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Guest Editorial

Widespread HIV Antibody Testing of Pregnant Women—How Accurate?

A landmark clinical study demonstrates that treatment with Zidovudine of pregnant women infected by human immunodeficiency virus (HIV) and their newborns greatly reduces perinatal transmisson.[1] Several other studies show that targeted testing of at-risk women misses many HIV-infected pregnant women.[2] In light of these findings, the Centers for Disease Control and Prevention (CDC) recommend that *all* pregnant women be offered voluntary HIV testing. The Connecticut Department of Public Health (DPH) concurs with the CDC and recommends that all pregnant women be tested for HIV.

This recommendation raises the question of how often false positive or indeterminate HIV antibody results arise from widespread HIV antibody testing of pregnant women. This is an important question and is worth reviewing. It was considered carefully by CDC staff and expert consultants during the drafting of the CDC recommendation. While various techniques, such as viral load testing, are approved for monitoring therapy, HIV antibody tests are still generally used for initial diagnosis of HIV infection* and will be the focus of my analysis.

Bayes' theorem, derived from probability theory, can be used to determine the predictive value of a positive HIV test in a pregnant woman and to estimate the likelihood of a false positive test result.[3] The predictive value takes into account the sensitivity and specificity of the test and the true prevalence of HIV infection in the population, which can be estimated in pregnant women by the Survey of Childbearing Women. In Connecticut, HIV prevalence in pregnant women was estimated to be 2.15 per 1,000 in 1995; with an HIV antibody test sensitivity of 99.4% and specificity of 99.99%, Bayes' theorem indicates that only four per 1,000 HIV-positive pregnant women in our state would be false positives, while the remaining 996 HIV-positive pregnant women would be *true* positives. During 1995, an estimated 92 HIV-infected women bore live children in Connecticut; therefore, it would take almost three years on average to encounter a false positive in this state. Most physicians caring for pregnant women will never encounter one. The predictive value of positive HIV antibody tests in Connecticut will be better than the predictive value of positive HIV antibody tests in volunteer blood donors. While one in 20 volunteer blood donors testing seropositive for HIV is a false positive,[4] Bayes theorem indicates that only one in 250 HIV-positive pregnant women in Connecticut will be.

Indeterminate HIV antibody test results are more common than false-positive results. Gwinn et al reviewed data from the Survey of Childbearing Women from 20 state laboratories across the nation.[5] They found that fewer than one in 4,000 HIV antibody tests of pregnant women were indeterminate. Only 9% of samples testing repeatedly reactive on EIA were indeterminate on Western Blot (WB) confirmatory testing. Gwinn also found that the rate of indeterminate results did not vary by the seroprevalence of the population of pregnant women, so in very low prevalence states indeterminate results in pregnant women could outnumber HIV antibody test positives. However, in Connecticut, one of the highest prevalence states in the country, the opposite is true. If all pregnant women were tested in Connecticut, one would expect 70 to 90 positive tests and 10 or fewer indeterminate HIV antibody test results among pregnant women each year. Indeterminates may occur during seroconversion, or they may be due to cross-reacting antibodies, such as antibodies to fetal white blood cells. Cross-reacting antibodies is a more likely cause of an indeterminate result than seroconversion in a low HIV-prevalence population.[6]

It is also possible that a "false positive" or an "indeterminate" test could be due to specimen labeling or laboratory error. The likelihood of such errors occurring depends on quality control in the medical facility and laboratory.

CDC emphasizes the importance of following the correct testing algorithm when interpreting test results and when determining a course of clinical action; repeatedly reactive EIAs must be confirmed with a more specific second test, such as a WB or immunofluorescent antibody (IFA). CDC does not advise routine repeat testing of all newly identified seropositives. However, in some circumstances, repeat or additional testing may be appropriate. For instance, it would be reasonable to retest a patient with a positive test result without discernible HIV risk. Retesting should also be considered if other factors, such as an undetectable viral load before initiation of antiviral therapy, makes the clinician suspicious of the veracity of the test result.

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*The recommended testing algorithm is first screening with the highly sensitive Enzyme-linked Immunosorbent Assay (EIA). A blood sample with a reactive EIA should be retested twice. If one or both af the EIA retests is also reactive, the sample should be tested with a confirmatory test such as the Western Blot (WB) or Immunofluorescent antibody (IFA). The whole algorithm is usually performed on a single blood sample.

The CDC does recommend immediate retesting of women with indeterminate HIV antibody test results. If the second result is indeterminate, then additional tests, such as polymerase chain reaction, should be considered. Confirmation of the EIA with IFA instead of WB may be performed, because IFA is less likely than WB to give an indeterminate result. A patient who has repeatedly reactive EIAs that do not confirm by WB or IFA, should be considered uninfected. Diagnostic follow-up should be completed and the patient's infection status clarified before proceeding with clinical interventions such as antiviral therapy.

Widespread prenatal HIV testing has costs: the expense of the tests, the stress of waiting for a result, the occasional indeterminate, and the rare false positive. However, these costs must be weighed against the cost to the mother and the child of delayed diagnosis of maternal infection and the lost opportunity to intervene when HIV infection in the newborn might have been prevented.

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50 Years Ago

From *The Connecticut State Medical Journal*

October 1948

The Candidates Speak

Governor Dewey

"Compulsory, socialized medicine is no good. It cannot be done. Accordingly I have spent the last two years of my life knocking down every proposal that anybody has made to regiment the medical profession and the people of America through any program of socialized medicine. By making speeches publicly at every meeting of people that would listen to me on the subject, I have made clear that we have actually been through this thing, this thing which cost the people of my state $200,000 to find out about. I don't want the money wasted. I don't want to run the risk of happening to the health of our people what has happened to the health of every group of people which has tried to drag the medical profession down to the Socialists' level. You won't drag anything up. You will enlarge the volume of medical care but utterly destroy the quality of medical care the minute you try that process.

"Now, some people come to me and say this is just a negative approach, Governor. What do you suggest? Well, my first answer is that if a thing is evil, the first job is to convince people that it is evil and thoroughly evil and destroys everything that we believe in. Then if you have succeeded in doing that, and can get out of their minds that by passing a law you can magically create something which does not now exist, you have made most of the progress. You know, we Americans are the greatest passers of law to solve problems in the world....

"This idea which has been shared by the last two occupants of the White House that you can improve medical care by passing a law must be stopped. We must get vast broad educational ideas to the people, as to the quality of care that now exists and as to a greater program that is going forward by men of medicine, we must have a program all can take a share in. Let's get some good public relations men and get the business man to do his share and get the lawyers and the labor leaders and everybody else. They are the ones who will lose most of all, if freedom in medicine is ever lost.

"Let's get them all understanding and working and they won't want to be putting you in jail with socialized medicine. I am unalterably opposed to it. It won't work and will lower our standard, and I venture our death rate would mount from the very day it was passed. I think there is a positive approach. I don't think the doctors ought to have to handle that approach but you do have to stimulate other people to take part in this job and lead the parade."

President Truman

"The greatest gap in our social security structure is the lack of adequate provision for the nation's health.... I have often and strongly urged that this condition demands a national health program. The heart of the program must be a national system of payment for medical care based on well tried insurance principles.... Our ultimate aim must be a comprehensive insurance system to protect all our people equally against insecurity and ill health.

"Such a system of (required) prepayment should cover medical, hospital, nursing, and laboratory services. It should also cover dental care—as fully and for as many of the population as the available professional personnel and the financial resources of the system permit. The ability of our people to pay for adequate medical care will be increased if, while they are well, they pay regularly into a common health fund, instead of paying sporadically and unevenly while they are sick. This health fund should be built up nationally, in order to establish the broadest and most stable basis for spreading the costs of illness, and to secure adequate financial support for doctors and hospitals everywhere. If we were to rely on state-by-state action only, many years would elapse before we had any general coverage ...

"I am in favor of the broadest possible coverage for this insurance system. I believe that all persons that work for a living and their dependents should be covered under such an insurance plan. This would include wage and salary earners, those in business for themselves, professional persons, farmers, agricultural labor, domestic employees, and employees of nonprofit instituitons and their families. In addition, needy persons and other groups should be covered through appropriate premiums paid for them by public agencies."

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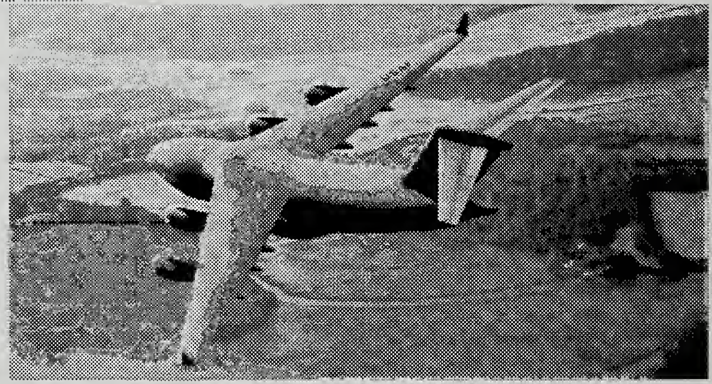

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Rising Health-care Costs and Physician Unity

A recent report by the Department of Health and Human Services predicts that total health expenditures will rise from approximately 1 trillion dollars in 1996 to 2.1 trillion in 2007, a little over eight years from now. The percentage of the gross domestic product will increase from 13.6% to 16.6%. Those percentages are greater than any other country in the world.

The figures do not take into account that the majority of the baby boomers in 2007 will not have reached their late 60s or 70s when they will begin using health-care services at a still higher rate. They also cannot account for the technological advances which we may see in the near future. The implications of the genome project together with current cancer and cardiovascular research are astounding. Those advances will not be cheap, however. If they do prolong our lives, expenditures on health care will go up even more.

Increases in health-care costs have been fairly flat over the past few years. This is a one-time occurrence which represents more and more people joining managed-care plans. The plans, in turn, have squeezed discounts out of physicians and hospitals. However, patients still expect unlimited access to any form of treatment available. Physicians and hospitals can only be squeezed so far. Even doctors, who are not known for their business savvy, will finally realize that one can't lose money on each unit (patient) but make it up in volume.

The insurance companies will respond by raising premiums. This will begin after they are consolidated into just a few companies in each area. Connecticut has about 17 managed-care companies but this will not last. Rising premiums will, however, add to another problem, namely the uninsured. We currently have about 41 million uninsured Americans, up about 10 million from when the Clinton health-care plan was being debated. As premiums go up, businesses will pay for them by increasing costs to consumers and by screaming bloody murder to Congress. Health-care availability, already informally rationed, will begin to see formal limits placed on it.

The question for physicians is how to respond to these changes. We are at a competitive disadvantage because we have been trained to be competitive and to value autonomy. That is, we are most comfortable with the "captain of the ship" model. Valuing autonomy means that we distrust others speaking for us, and we are conversely hesitant to speak for others. Proof? Look at our medical associations and many of the physician groups that are now forming. The "troops" are constantly griping about the leaders yet the troops always seem to have a reason why they can't step into leadership positions themselves.

At the risk of repeating an old cliché, the only constant in life is change. Bigger changes than ever heretofore seen are on the way. Not only are the old days gone and not coming back, today will be gone before we know it. Burying our heads in the sand or railing against the injustice of it all will get us nothing. Physicians will either organize and learn to trust their peers or we will be like most other commodities, easily bought and sold.

Craig W. Czarsty, M.D.
President

UNITED STATES POSTAL SERVICE™

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3. Be sure to furnish all information called for in item 15, regarding circulation. Free circulation must be shown in items 15d, e, and f.
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Failure to file or publish a statement of ownership may lead to suspension of second-class authorization.

PS Form 3526, October 1994 *(Reverse)*

Signs of the Times?

ROBERT U. MASSEY, M.D.

DURING the summer I read and found myself agreeing with Daniel Callahan's book, *False Hopes,* in which he called for an equitable, steady-state, sustainable medicine. His advocacy for defining limits recalled the lively debates 25 years ago concerning zero population growth and zero economic growth, the need to set limits, to build a stable global society. Do you remember the Club of Rome? The recent declining vigor of the bull market and the foundering of economies around the world, the failure of unbridled capitalism in Russia, along with wars and rumors of wars, suggest that just maybe we are seeing, without discerning "the signs of the times," a kind of global readjustment, a retreat to the center, a clumsy settling down to rest awhile, even a muffled "enough already." But I doubt it.

Last month's *National Geographic,* in its bland, we-never-take-sides kind of way, raised once again the population problem, one billion new editions of Homo sapiens every 12 years, with no slowdown in sight.[1] According to UN projections, the developed world will lose population slowly, sliding from 1.18 billion today to 1.16 billion by 2050, hardly noticeable, in fact, a steady state. But the undeveloped world's population will rise from today's 4.75 billion to 8.2 billion by 2050. I recall when the global population was two billion, and the United States had only 120 million people. Twenty-five years ago we worried that we were close to the planet's carrying capacity, that food production had reached its maximum, that we would shortly hear of massive famine throughout the developing world, and would see starving infants on our television screens. An eminent NSF scientist advised that we should then turn the tube off, watch something else, because nothing could be done about it.

Since then farmers in the United States and Canada, who now count for less than 3% of our population, have doubled their output of agricultural products, especially grain; and not only that, the green revolution has spread almost everywhere, not limited to North America. All that doomsday stuff in the late 1960s and 1970s was premature, if not dead wrong.

But still the worry lingers; there *must* be limits—limits to arable land, to water, to energy, to human resourcefulness, human patience and charity, and human adaptability. A world population of 9.36 billion by 2050, maybe 12 billion by 2100 even if birth rates slow a little, might well exceed the resources of this small planet that is already overheating. Even now, according to the *Geographic,* 20% of the developing world's people are undernourished, and even in America 30 million go to bed hungry. In the past human beings, like other species, faced real limits, mostly set by the four miserable horsemen: plague, war, famine, and (early) death. Infant mortality was the most efficient of all until the inversion of mortality began in the West sometime after 1850, death arriving in old age rather than in infancy.

Unless the world powers can get together on all this, always an unlikely prospect, the four unholy riders will return, but in a more technically elegant guise, man-made mostly.

Daedalus, the Journal of the American Academy of Arts and Sciences, published three issues in the 1970s that dealt with three aspects of this limits matter: Fall 1973: "The No-Growth Society"; Winter 1977: "Doing Better and Feeling Worse: Health in the United States"; and Spring 1978: "Limits of Scientific Inquiry."

Schemes for dealing with population growth or the extremes of wealth and poverty, improving the distribution while pruning the exuberant growth of medical care, or limiting the spread of unneeded, unwanted technology, all may involve some kinds of governmental control, then coercion, and then central planning with its inevitable bureaucratic corruption and legalized tyranny. Schemes and programs, clear solutions to large problems, are almost always flawed, creating far more grief than they are designed to relieve. Even *Daedalus's* scholarly authors often did not agree either on whether the problems existed, or, if they did, what to do about them.

I cannot resist quoting Aaron Wildavsky, who at that time was dean of the Graduate School of Public Policy, University of California, Berkeley. His paper, "Doing Better and Feeling Worse: The Political Pathology of Health Policy," begins:

> According to the Great Equation, Medical care equals Health. But the Great Equation is wrong. More available

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ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

> medical care does not equal better health. The best estimates are that the medical system (doctors, drugs, hospitals) affects about 10% of the usual indices for measuring health.... Most of the bad things that happen to people are beyond the reach of medicine.

And he concludes 17 pages later:

> Health policy is pathological because we are neurotic and insist on making our government psychotic. Our neurosis consists in knowing what is required for good health (Mother was right: Eat a good breakfast! Sleep eight hours a day! Don't drink. Don't smoke! Keep clean! *And* don't worry!) but not being willing to do it. Government's ambivalence consists in paying coming and going: once for telling people how to be healthy, and once for paying their bills when they disregard this advice. Psychosis appears when government persists in repeating this self-defeating play. Maybe 21st-century man will come to cherish his absurdities.[2]

Lewis Thomas in his article "On the Science and Technology of Medicine," echoed this sentiment and noted that in the last 25 years (1950–1975), not much had changed except that medical care had become more expensive, more dependent on half-way technologies, and that patients had even more unrealistic expectations:

> Nothing has changed so much in the health-care system over the past twenty-five years as the public's perception of its own health. The change amounts to a loss of confidence in the human form. The general belief these days seems to be that the body is fundamentally flawed, subject to disintegration at any moment, always on the verge of mortal disease, always in need of continual monitoring and support by health-care professionals. This is a new phenomenon in our society....
>
> There is, regretably, no discernible counter-propaganda....
>
> The system is being overused, swamped by expectant overdemands for services that are frequently trivial or nonproductive.... Medicine is surely not in possession of special wisdom about how to live a life.[3]

Today, 24 years later,Thomas would, I believe, see this obsession with health continuing to grow like a weed, at least in America. Some of my Canadian and European friends tell me that it's not like this back at their place, but I'm not so sure. See the president's page in this issue; Dr. Czarsty cites predictions that health-care costs will double, rise to 2.1 trillion dollars by 2007, 16.6% of the domestic product!

Kenneth Boulding wrote:

> The human race indeed is passing through what I have called a "crisis of closure," with the realization that it is expanding, both in numbers and in artefacts, into a niche which is by no means infinite although it is still quite large. The "shades of the prison house" of earth are closing in upon us, and we realize that the process of expansion, which has been going on now for perhaps a hundred thousand years, will very shortly, as reckoned by historic time, come to an end. [4]

He suggests that we have a century, more or less, by which time we will have a space-ship economy "in which all materials must be recycled and in which ultimately the sun is the only source of energy." That was written 25 years ago. The classical economists from Adam Smith on, according to Boulding, believed that the steady state was the "normal" state, but was "dull," and when it went into decline, "dismal."

Social planning always fails. Both Soviet Communism and German National Socialism failed only after producing incredible misery. Johnson's Great Society failed, so has school busing, and so has managed care. I believe that one of the secrets of Great Britain's general success and sanity since the 16th century has been the British genius for "muddling through."

You will recall William Osler's misquotation of Carlyle: "Our duty is not to *see* what lies dimly at a distance, but to *do* what lies clearly at hand." No long-term planning! Our fellow species, by muddling, do figure out how to live within their niches—or else they disappear. We're not likely to do that soon!

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This Month's Reading in Review

TIMOTHY B. NORBECK

Americans' growing concerns about managed-care plans have helped the medical profession hold on to first place in ratings for 17 occupations, according to a recent Louis Harris & Associates survey.... Sixty-one percent of respondents see physicians as having "very great prestige," as compared to 52% last year.... It is the highest score physicians have achieved since 1977.... Pollsters suggest that the increase in stature reflects the public's belief that physicians often act as patient advocates in disputes with health plans.... In the poll, scientists finished second behind physicians, followed by teachers, the clergy, and police officers.... As for the lowest in public esteem: journalists, union leaders, accountants, bankers, and businessmen.

Medical Economics (10 August 1998)

Former Surgeon General C. Everett Koop, while speaking at Southern Illinois University, "condemned managed health care, saying it sacrifices the needs of patients for the financial bottom line of insurance company investors.... He stated that "We must arrest the trend ... of taking the medical decisions of patients out of the hands of physicians and placing them in the hands of businessmen."

St. Louis Post Dispatch (13 September 1998)

"Hold the Onions..."

A French chef "is now offering a dish sauced with" Viagra.... *The London Evening Star* reports that chef Jean-Louis Galland's Haute-Savoie restaurant is located near the border with Switzerland "where the drug is bought over the counter."

New York Post (21 August 1998)

Syndicated columnist Jane Bryant Quinn argues that none of the current HMO reform proposals to make health plans more accountable are sufficient.... By denying treatment, she says, HMOs increase their profits with almost no risk of loss if they make a mistake.... "Market incentives are wrong, and whether you appeal to the law or arbitration, the deck is stacked against you."... Quinn contends that there's a better solution than a complicated appeals process: no-fault health insurance.... "Everyone injured would be compensated by the medical plan's insurer, with no lawsuits involved. The medical plan's premiums would be linked to the claims paid."

Akron Beacon-Journal (25 August 1998)

Smoking costs the U.S. health system 72.7 billion dollars a year, according to University of California-San Francisco researchers.... The researchers analyzed financial and population data in three large federal databases, tallying costs associated with five medical conditions, including lung cancer, heart disease, and stroke, for the population 19 and older.... Overall, they found that smoking cost[s] the nation 11.8% of its 614 billion dollars spent on health care in 1993.

Contra Costa Times (10 September 1998)

Editor's Note: The numbers must be higher now, since that 614 billion dollars spent in 1993 has risen to over 1 trillion dollars.

Medicare Statistics (Medical Management Institute)

- 50% of practices do not appeal denials.
- There is a 30% chance of denial on submitted claims.
- Nine months is the average duration of employment for a Medicare claims processing clerk.

Vital Signs (August 1998)

Would You Believe?

A retired Vermont dairy farmer, who spent less than 200 dollars on his campaign, defeated a millionaire corporate consultant to win the Republican nomination to oppose incumbent U.S. Senator Patrick Leahy in the November election.... Fred Tuttle, 79, captured 55% of the vote.... His biggest campaign event was a nickel-a-plate fund-raising dinner at his house in which most of his 200 dollar budget went to renting portable toilets.

Associated Press (9 September 1998)

"Facing competitive pressure to keep beds full, and in an era of heightened consumer awareness about health care, hospitals have drastically increased their advertising in the past two years.... Hospitals nationwide allocated a staggering 1.28 billion dollars to advertisements last year, representing a 32% increase over the previous year.... The Opinion Research Corporation International found that the average hospital expenditure on advertising last year was 257,800 dollars.... This figure compares with 195,100 dollars in 1996 and a "virtually nonexistent" advertising budget in 1984.

The Boston Globe (25 August 1998)

Only in America:

In a May report, the *New York Times* revealed that the town of Aspen, Colorado, apparently desperate for people other than millionaires to live there, offers public housing assistance even to those whose income is as much as 115,000 dollars a year.

News of the Weird (8 September 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

From the Executive Director's Office

COUNCIL MEETING

Wednesday, 26 August 1998

Attendance

Present, in addition to the chairman, Dr. Hollister, were Drs. Ahamed, Aleali, Beck, Bigos, Bobruff, C. Czarsty, J. Czarsty, Deren, Eslami, Franklin, Geary, Geist, Handelman, Herzog, Katz, Keating, Lesnik, Maloney, Redmond, Sachs, Sadowski, Sosa, Van Linda, and Wetstone.

Also present were: Mr. Norbeck, Ms. Lindquist, Mr. Brunell, Ms. Morelli, Mr. Staples, Ms. Norbeck, (all CSMS staff), Mr. Thompson (FCMA staff), Mr. A. Schuman, Mr. M. Schuman, (NLCMA, WCMA, MCMA, and TCMA staff), Mr. Coffey, Mr. Fiorentino (HCMA staff), Dr. Genel (CURE), Dr. Thompson, Mr. Lalime (CSMS-IPA), and Dr. Jessee (AMA-AMAP).

Absent were: Drs. Brooks, Carolan, Conant, Montegut, Narayanan, Scarpa, Schwartz, Sindwani, Tesoro, Timmerman, and Turner.

Reports of Related Organizations

CSMS-IPA: At the 25 June meeting, the Council requested that they be provided with additional information relating to the operational and financial status of CSMS-IPA. A comprehensive report from the CSMS Board of Directors was distributed with the agenda, outlining the CSMS-IPA background, program review, flow of premium dollars, review of premium structure, statistical review of professional expenses and utilization, summary of utilization experience, current situation, and initiatives for corrective action. It was VOTED to accept the report for information.

Dr. David Thompson, president of CSMS-IPA, also reported on some of the history of the CSMS-IPA and distributed a document which included information covering its beginning, the merger of MD Health Plan, and how it affected the IPA and negotiations that are now underway with the HMO to obtain a higher percentage of the premium dollars. He stated that the goal that the IPA began with can be maintained and it can be in charge of its own destiny. All decisions about medical care and all mechanisms that will be used to provide medical care in the most efficient means possible can be made by the IPA. He further stated that the Board of Directors of the CSMS-IPA looks to the CSMS for guidance and support. It was VOTED to receive the report as information.

Following the CSMS-IPA presentations, Dr. Thompson and Mr. Ken Lalime, the IPA executive director, participated in a lengthy question-and-answer period. The chair thanked Dr. Thompson and Mr. Lalime for their presentations, stating they were very informative. Mr. Laline informed the Council that this report was a beginning, and it was his intent to make ongoing reports to the Council.

Nomination and Election Process of the CSMS-IPA Board: Cam Staples, CSMS legal counsel, and Ken Lalime, executive director of the CSMS-IPA, reported on the history of the nomination and election process of the CSMS-IPA Board of Directors. They reported that a series of irregularities occurred in the 1998 nomination process and recommended that the 1998 nomination and election process of the IPA be rerun more closely following the IPA bylaws. They indicated that it was their intent to bring a more detailed nominating and election proposal to a future Council meeting to be followed in accordance with the CSMS-IPA bylaws. Following lengthy discussion, it was VOTED that a meeting of the shareholders of the CSMS-IPA be held on the day of the next Council meeting which is Thursday, 15 October.

Report of the President

Dr. Czarsty reported on the two amicus briefs that were authorized by the Council as follows:

One was on peer review protection, and he stated that CSMS had been granted intervenor status, with the deadline for filing the brief 4 October. Oral arguments will be held in November, and legal counsel preparing the brief will provide CSMS counsel with a draft of the brief.

The second brief is in regard to the ThermoLase Corporation's appeal of the state's decision that the use of lasers is a medical procedure and can be performed only by physicians or their designees. The state is taking the lead on this issue, and CSMS has been granted intervenor status. A draft of the brief, which will have to be filed in early September, will be provided to CSMS counsel.

In accordance with the request of the Council, the president filled the following vacancies:

Connecticut Physicians' Guild: Dr. Roger Beck and Dr. Michael Deren were appointed to fill two vacancies: Robert McDonnell, M.D., deceased, and Frank Abbot, M.D., who moved out of the state.

Committee on Ethical and Judicial Affairs: John Franklin, M.D., to fill the unexpired term of Todd Anderson, M.D., who resigned.

At the last meeting, it was voted that the president appoint a committee to meet with Dr. Parke to help him interact with the Department of Public Health on the issue of surgicenter regulations. Dr. Czarsty appointed the following Surgicenter Task Force: Frank Scarpa, M.D., Chair; Kristin Zarfos, M.D., David Parke, M.D., Robert Greenberg, M.D., and Marvin Arons, M.D. He stated that Ms. Morelli would be staffing this group and asked that she convene a meeting in time to have recommendations for the Committee on Legislation and the Council.

He reported that following the Council meeting, a meeting was to be held to interview four candidates for the position of Editor of *Connecticut Medicine*, to replace Dr. Robert Massey, who has expressed his wish to resign.

The Council was informed that the meeting Dr. Czarsty had held with the county presidents was well received, based on comments that evening and several letters he received following the meeting.

Two primary issues that were raised were the IPA and the relationship between the counties and CMIC. A meeting with representatives of CMIC and county officers and executive directors was suggested and has already been arranged for 10 September.

Since Dr. Herzog was not at the last Council meeting, Dr. Czarsty extended congratulations to Dr. Alfred Herzog, Councilor from Hartford County, who was elected speaker-elect of the Assembly of the American Psychiatric Association.

He also noted that Neil Brooks, M.D., was appointed by AMAP to the Performance Measurement Coordinating Council. The establishment of the Council is the first step in a collaborative effort, launched in May by AMAP, JCAHO, and NCQA to coordinate important aspects of performance measurement activities across the entire health-care system. The goal of the Council is to ensure that performance measurement processes are efficient, consistent, and useful for the many parties that rely upon them to make decisions about health care.

Report of the Executive Director

Mr. Norbeck reported on the following items:

CIGNA Deselection Case: It has been previously reported that CIGNA dropped physicians and the physicians brought suit against CIGNA in Superior Court, where Judge Blue dismissed the case in December 1994. The case was appealed to the Connecticut Supreme Court which reversed the trial court's action in 1996. The case was settled out of court and the physicians were reinstated and CIGNA paid an undisclosed sum to them. The Council should feel especially good about the results because Dr. Napoletano and the other physicians were thinking seriously about not appealing the Superior Court dismissal until CSMS offered to file an amicus brief and provide funds to help them defend their position.

Medicare: Medicare will change again on 1 January 1999, and go from its present form of Part A and B and the Medicare Risk HMO to Medicare Plus Choice which includes more options, such as:

Point of service plan
Preferred provider organization
Provider sponsored organization (PSOs)
Medical savings account—(MSAs) (effective 1 November)

It was reported that some claim that MSAs are not good and are not working. It is said that fewer than 100,000 people have signed up for them, far fewer than the 750,000 accounts allotted in the 1996 Federal Health Insurance Portability Law which implemented MSAs (the Kassebaum/Kennedy Bill). Others claim that MSAs have not caught on because there are stiff financial penalties for nonhealth purposes, and they are not available to workers whose companies employ more than 50 people. Not a single company has met the 15 August deadline for applications to begin selling MSAs to seniors in November.

Since Dr. Timmerman, COMPAC chair, was unable to be at the meeting, Mr. Norbeck repeated his plea that support is desperately needed from physicians. The present number is now 608 out of 7,000 members. It is important to increase COMPAC funds, so that COMPAC can participate in fund raisers and also participate in every House and Senate race in Connecticut. He asked the councilors to spread the word among their colleagues that their contributions will translate into support for medicine. According to the Annenberg Public Policy Center of the University of Pennsylvania, the top five issues used by outside groups to rally either support for or against a candidate are: Medicare, government spending and budget, taxes, abortion, education.

Mr. Norbeck reported that managed care has helped the medical profession to hold on to its first-place rating in public regard of 17 occupations. Sixty-one percent of Louis Harris survey respondents see physicians as having "very great prestige." That is up from 52% last year and is the highest score physicians have had since 1977. Pollsters suggest that the increase in doctors' stature reflects the public's belief that physicians act as patient advocates in disputes with health plans. Behind physicians in public stature were scientists, teachers, clergy, and police officers.

The Hartford Insurance Company published a vicious advertisement relative to workers' compensation suggesting that physicians have been ripping off the consumers.

AMA sent a sharp letter to the Hartford CEO and received an apologetic letter from The Hartford indicating that they agreed it was inappropriate, should never have been produced,will no longer be used, and have prohibited its reproduction in any form.

Conflict of Interest

Two items were submitted by the Committee on Ethical and Judicial Affairs to the Council for approval:

(a) Proposal Regarding Disclosure of Conflict of Interest:

It was VOTED to approve the following statement:

"All persons nominated for positions as officers and committee chairpersons of the Connecticut State Medical Society shall disclose, for publication in the Delegates Handbook prior to the election, any and all business relationships with insurance and managed-care entities, other than the usual 'third party' practice relationships."

Additionally, this information shall be published annually in *Connecticut Medicine*, together with the same information for all members of the CSMS Council as well as senior management of CSMS."

(b) Conflict of Interest Policy:

It was VOTED to approve the seven-page document submitted by the committee. (The document is published following these minutes on page 633.)

Report on American Medical Accreditation Program (AMAP)

At its 25 June meeting, the Council requested the executive director to work with the Connecticut Medical Insurance Company (CMIC) and AMAP to develop a proposal to implement AMAP in Connecticut for consideration at this meting. A comprehensive written report of a meeting held for this purpose was provided the Council. The meeting included county representatives, CMIC representatives, and CSMS staff. William F. Jessee, M.D., vice-president, Quality and Managed Care, AMA-AMAP, attended the meeting and presented an overview of AMAP. It was VOTED to accept the minutes of the meeting as information.

Dr. Jessee attended the Council meeting and presented an in-depth explanation of the AMAP program, outlining the rationale and propriety of how the AMA got into the business of setting standards and accrediting individual physicians, how the program works, and how it would relate to CSMS in the development of a program in Connecticut. Following a question period, it was VOTED that CSMS enter into a partnership agreement with the AMA to implement the AMAP program immediately.

Dates of Future Meetings

Council Meeting
Thursday, 15 October 1998

CSMS-IPA Shareholders Meeting
Thursday, 15 October 1998.

Semiannual Meeting—House of Delegates
Thursday, 19 November 1998

Annual Meeting—House of Delegates
Wednesday, 12 May 1999

Semiannual Meeting—House of Delegates
Wednesday, 17 November 1999

Connecticut State Medical Society Conflict of Interest Policy

Adopted by the CSMS Council on 26 August 1998

MEMBERS of the Connecticut State Medical Society (CSMS) Council, Officers and Directors of the CSMS, and members of CSMS committees (hereinafter collectively referred to as "Officers") bring to the CSMS expertise drawn from their diverse knowledge and backgrounds. The CSMS recognizes that, at times, the diverse background and activities of its Officers may conflict with the interests and activities of the CSMS. CSMS Officers hold a special position of responsibility to the Society, and owe a fiduciary obligation to act in the best interest of the Society. Officers have a responsibility to place the achievement of CSMS's goals and mission above any other competing interests.

The CSMS adopts this Conflict of Interest Policy to provide guidelines to assist the CSMS Officers in resolving conflicts between the interests of the CSMS and any personal, organizational, or other competing interest. This Conflict of Interest Policy strives to insure that Officers will not act for their own personal benefit or the benefit of other organizations which may have conflicting interests to those of the CSMS, but instead will serve the best interests of the CSMS at all times.

Although not elected, members of Senior Management are also expected to serve the best interests of the CSMS. Conflicts of interest may arise from Senior Management's affiliations with other organizations, or from other personal activities. It is important for the CSMS Council to be aware of any affiliations or activities which may raise conflicts, as Senior Management is responsible for advising the Council and making recommendations on CSMS policies and activities. Senior Management shall also abide by these guidelines to the extent they are applicable.

For purposes of this policy, the term "CSMS" or "Society" shall mean the Connecticut State Medical Society and shall include the following subsidiaries: CSMS-IPA, Physicians Health and Education Fund, The Physicians Guild, The CSMS Charitable Trust, CSMS Plus, and MD Advantage (provisions applicable to CSMS Board members).

Guidelines

Ownership of a material financial interest in any company that furnishes goods or services, or is seeking to furnish goods or services, to the CSMS.

An Officer shall disclose his or her ownership of a material financial interest in any business which furnishes goods or services, or is seeking to furnish goods or services, to the CSMS. An Officer shall also disclose material financial interests owned by any members of the Officer's immediate family.

The CSMS recognizes that individuals have investments, through stock ownership, mutual funds, and similar vehicles, in companies that provide goods and services to businesses. Only those investments that constitute a significant financial investment raise a concern about a possible conflict of interest. The CSMS also recognizes that an Officer may be employed by, or have a consulting arrangement with, an organization that does business with the CSMS. A conflict of interest may arise if the Officer holds a key position in such a company and is responsible for approving the provision of goods or services to the CSMS. Accordingly, "ownership of a material financial interest" shall mean holding a financial ownership interest of 5% or more, or holding a financial ownership interest which contributes materially to the Officer's income, or holding a position as proprietor, director, managing partner, or key employee.

An Officer shall excuse himself or herself from discussion and vote on any issues relating to the provision of the goods and services by any company in which the Officer or any immediate family member owns a material financial interest.

Participation as an Officer or Member of Boards, Councils or Committees of other organizations.

Participation by CSMS Officers as officers or members of boards or committees of other organizations is beneficial to the Society, as the Officers gain important expertise and establish business relationships. To insure that the Officer is not placed in the difficult position of serving organizations with conflicting overall goals and objectives, an Officer shall disclose his or her participation in other organizations. If the overall goals and objectives of the CSMS and the other organization do not conflict, participation is permitted. If a conflict exists, the Officer shall choose between the conflicting organizations, and shall resign from one of the positions.

However, even when the goals and objectives do not conflict, a conflict of interest may arise when an Officer has fiduciary or other obligations to more than one organization and those obligations conflict. These conflicts may arise when an Officer has a duty of loyalty to CSMS and another organization and a matter arises at one organization that could detrimentally affect the interests of the other. In such cases, the Officer shall refrain from participating in any actions or matters for either organization that might affect the other. If conflicts between the duties to the two organizations are frequent and intense, the Officer may need to resign from one organization.

Other personal relationships, activities, or interests which may inappropriately influence an Officer's decisions or actions on CSMS matters.

Situations may arise, from time to time, where an Officer is unable to separate his or her personal interest in an issue from his or her obligation to objectively serve the interests of the CSMS. To insure that the Officer's fiduciary obligations to the CSMS are met and that the interests of the CSMS are paramount, disclosure of any such personal interests is required. However, it is important to keep in mind that Officers will frequently have a personal interest in and opinion on the issues that come before them. A general requirement that Officers be excused from discussions on any issue in which he or she has a personal interest may diminish the benefits that CSMS receives from full, informed debate. However, if an Officer's ability to render a fair and independent decision is jeopardized by the conflict between their personal interests and the interests of CSMS, the Officer shall excuse himself or herself from discussion and/or vote on the issue. If a Officer or Member does not appropriately excuse himself or herself, but the majority of the remaining Officers or Members believe that the Officer or Member should be excused from either discussion or vote, the Chair shall require the Officer or Member to excuse himself or herself from discussion and/or vote.

Disclosure of Confidential or Proprietary Information

In the course of performing services to the CSMS, the Officers will have access to information that is confidential or proprietary to the CSMS. This information includes, but is not limited to, financial information, business plans, policy proposals and recommendations, policy development plans, confidential membership plans, and other information which may impede implementation of CSMS activities if it were disclosed. An Officer shall maintain the confidentiality of such information and shall not disclose confidential or proprietary information for any purpose. An Officer shall use his or her best efforts to prevent unauthorized disclosure of confidential or proprietary information.

Interpretation

The Conflict of Interest Policy is intended to be an evolving policy, and questions of interpretation and application can be expected to arise. Conflict of Interest Principles have been developed to provide guidelines in resolving conflicts.

Implementation

Each Officer shall execute annually a Compliance Statement, confirming that, to his or her knowledge, the Officer has complied with the Conflict of Interest Policy, and disclosing any matters required to be disclosed under the Policy. The Executive Director of the Society shall be responsible for prescribing the time and manner for filing such Compliance Statements and for obtaining executed Compliance Statements. The General Counsel and the Committee on Ethical and Judicial Affairs shall review all disclosures made by the Officers. Each Officer shall have a continuing responsibility to comply with this Conflict of Interest Policy and to disclose any conflicts that may arise during their tenure.

If during Council or Committee deliberations, an Officer discloses an actual conflict of interest regarding a particular matter, he or she should leave the room during consideration of that item and take no part in the discussion or vote on the matter. If an Officer discloses a potential conflict of interest and seeks a determination as to whether abstention from participation in deliberations on the item is warranted, he or she should leave the room while the remaining members determine whether a conflict of interest exists.

If an Officer has reasonable cause to believe that another Officer has failed to disclose a personal or outside interest that could constitute a conflict of interest, he or she shall so inform the Officer of the basis for that belief, which Officer shall be provided an opportunity to address the Council to respond to the concerns expressed. The Chairman of the Council may appoint a Committee of the Council to investigate and report back its findings and recommendations concerning any claimed conflict of interest. The Council may determine, by majority vote, whether a conflict of interest exists. If a conflict is determined to exist, the conflicted Officer shall leave the room during deliberation on the matter in question and shall not participate in the discussion or vote on such item.

Gifts

To avoid any inference that a decision was unduly influenced, an Officer and members of the Officer's immediate family, may not offer, solicit or accept any gift, money, benefit, loan, or other payment of any kind from any entity with whom CSMS does business, with whom CSMS is seeking to do business, or from any entity seeking to do business with CSMS. The term "entity" includes, but is not limited to, financial institutions, business and professional firms, and individuals providing goods or services.

This provision is not intended to prohibit the following gifts or benefits:

- Acceptance or offering of nominal gifts, or social amenities and entertainment which are given in normal business practice and which would not raise an inference of undue influence.
- Acceptance or offering of gifts for a nonbusiness reason, and which are motivated by a family relationship or personal friendship.
- Benefits or discounts offered under any CSMS-sponsored program.
- Benefits or discounts which are offered as a professional courtesy to members of the medical profession, or to members of their immediate family, provided such benefits or discounts are not intended to influence a CSMS decision.
- Books, journals, audio or videotapes, computer software, or other informational material provided to assist the Officers in performing their duties for the CSMS.
- Payments received as compensation for services rendered or "ownership of a material financial interest," which are subject to other provisions of this Policy.

Honararia

Any honoraria received by an Officer for a CSMS-related engagement shall be given to the Society. Alternative arrangements may be allowed, provided that the Officer notifies the Chair of the Council and receives the Chair's prior approval.

Illegal Payments

An Officer shall not give any bribe, kickback, or any other illegal or improper payment of any kind to any person with whom the Officer comes in contact in the course of carrying out his or her responsibilities for the CSMS.

Use of Position or CSMS Name

An Officer shall not use the CSMS name, or his or her affiliation with the CSMS in a manner that would incorrectly imply a CSMS endorsement of a non-CSMS product or service, or that would imply CSMS support of a personal opinion or activity.

Activities Following Term

A former Officer shall not use the CSMS name or his or her affiliation with the CSMS, in any manner which would imply CSMS support or endorsement of policies or activities of another organization. A former Officer shall not use the CSMS name or his or her affiliation with the CSMS for commercial gain. A former Officer shall not disclose confidential or proprietary information for personal or commercial gain.

A former Officer shall refrain from all conduct, verbal or otherwise, which publicly disparages or damages the reputation, goodwill, or standing in the community of the CSMS or its Officers.

A former Officer shall also refrain from disparaging the CSMS. However, the expression of differences or disagreements with CSMS policies that are unrelated to his or her official actions as an Officer do not constitute disparagement.

BOOK REVIEW

Older … and Wiser?

Reading Engelhardt:
Essays in Honor of H. Tristram Engelhardt, Jr.
by Brendan Mingoue, Gabriel Palmer-Fernandez, and
James E. Regan (eds.), 320 pp. $110.00,
ISBN 0-7923-4572-X, Dordrecht, The Netherlands:
Kluwer Academic Publishers, 1997.

That the second edition of *Foundations*[1] is one of the most significant books about American bioethics to appear in this decade is confirmed by the collection of essays contained in *Reading Engelhardt.* In addition to an essay that nicely summarizes Engelhardt's message, there are 14 essays which, in one form or another, have taken Engelhardt on! The book concludes with an essay by Engelhardt himself, in which he responds to what the other essayists have written, and then briefly reiterates his basic message. Whether you love or detest Engelhardt, or even if you have never heard of him, this book is an important addition to your collection of American bioethics literature.

One reason these essays are useful is that *Foundations* itself is not an easy read. To his credit, Engelhardt writes about American bioethics by covering many issues and by situating American bioethics within the context of its ethical heritage. Those who think that bioethics amounts to the terms "autonomy, beneficence, nonmaleficence, and justice," will find Engelhardt's depiction daunting. *Reading Engelhardt* helps make *Foundations* reader-friendly. Not only do you get two summaries of what *Foundations* is all about (one by Engelhardt himself), you get all these reactions to it as well, all of which enables the reader to develop a better understanding of an important figure in American bioethics, and of American bioethics itself.

"American bioethics" is key to understanding the significance of Engelhardt's work and of these essays. According to a recent history of bioethics, Engelhardt is the "*enfant terrible* of bioethics: irrepressible, irreverent, unpredictable, but ever insightful and brilliant."[2] According to that same history, the "problem" with American bioethics is the "relative poverty of ethical theory in American bioethics."[2(p.379)] This collection of essays confirms both these points.

Engelhardt's basic message is that American bioethics is essentially "contentless." To the extent that we want a secure foundation on which to rest our judgments, there is either simply no "there there," or so much to choose from that one choice is as good as any other. While some think this makes Engelhardt a nihilist (a "bad" ethicist), his message reflects the solid metaethical critique of a "good" philosopher.

There being no way to adjudicate whose view of the good is best or even better, Engelhardt concludes that we must find a way to live amicably in a world of ethical strangers. He thinks we can do that, by using the principle of "permission," otherwise known as consent. Whether we live amicably or not, of course, depends on whether we are willing to make consent robust or not, to treat consent along conversational lines intended to enhance our understanding of one another, or along instrumental lines designed to insure that we prevail over "others."

What is interesting about these essays is how many writers respond to Engelhardt's solution by ignoring or disputing it. Mind you, no one disagrees with Engelhardt's description; but, with the exception of Stanley Hauerwas, no one embraces his prescription, or expands on what it may mean if we do not do the moral work that the principle of consent suggests we do. Instead, it seems either consent cannot do the job, or the job is somehow to keep doing what we have been doing. Thus, if one is looking for proof that American bioethics is intellectually impoverished, one should read, not Engelhardt, but *Reading Engelhardt.*

In this sense, this is the best of all possible books. Not only does it offer something for everyone; it offers "nothing" for anyone. After all, a conversational model of consent is likely to ring hollow in a nation that believes talk is cheap and that confuses argumentation with conversation. Why dialogue when one can mimic Firing Line? (It is ironic that so many people who detest lawyers speak to and about others in a strictly adversarial style.) If the choice we face is either to converse or perish, Engelhardt's closing observation, that our quest for meaning in the wrong places risks repeating the bloody history of this century, ought to give Americans and American bioethics reason for pause.

Giles R. Scofield, J.D.
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Professor, Recently Head,
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University of Connecticut School of Medicine
(1996–98)

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1. Engelhardt HT (ed.): *The Foundations of Biothics*, 2nd ed. New York, New York: Oxford University Press; 1996.
2. Jonsen AR: *The Birth of Bioethics.* New York, New York: Oxford University Press; 1998:82.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

Opportunities **should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians inquiring about such *opportunities*.**

Physicians wishing to locate **in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

Announcements on the Physician Placement Service page under Classified Advertising are charged at the regular Classified Advertising rate.

OPPORTUNITIES FOR PRACTICE

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Outstanding opportunity for board certified family physician/ internal medicine to join group practice in a personally and professionally gratifying environment on the beautiful Connecticut shoreline. Excellent growth potential. Please respond to: Alan M. Weiss, M.D., 652 Boston Post Rd., Guilford, CT 06437.

MEDICAL DIRECTOR— OCCUPATIONAL MEDICINE

Excellent opportunity for a BE/BC IM, GP, ER, OM, or GS to join this rapidly growing Occupational Medicine practice. Clinical or administrative responsibilities and experience in Connecticut worker's compensation, ADA and soft tissue injury management required. Extremely competitive salary, bonus and benefits package offered. For more information, send CV to the attention of Susan Henry, Industrial Health Care Company, 1095 Day Hill Rd., Windsor, CT 06095.

ONCOLOGY/ HEMATOLOGY

BE/BC oncologist/hematologist sought for new part-time position in a private practice (North Central Oncology Hematology Practice) affiliated with the new Johnson Community Cancer Center in Enfield, Connecticut. This is an established practice in a growth phase as we integrate with new radiation services and implement a comprehensive care program centered in a new spacious and attractive building on an existing campus which includes surgery center, VNA facility and office buidling. Johnson Memorial Hospital is the major hospital affiliation. Other practice affiliations (for academics, consulting or support services) include the University of Connecticut School of Medicine, St. Francis Hospital and Hartford Hospital. Please call Dr. Dennis Morgan (860) 763-4027, fax your CV (860) 763-4546, or write to NCOHP, 146 Hazard Ave., Enfield, CT 06082.

PART-TIME

Centrally located walk-in medical center, Bristol, Connecticut seeks part-time physician for limited hours per month. Contact Dr. Thomas Kandell or Dr. Ronald Falit at (860) 584-8900, 539 Farmington Ave., Bristol, CT 06010.

The Office of Hearings and Appeals, Social Security Administration, is seeking orthopedists who would be willing to serve as medical experts. We have five United States Administrative Law judges who preside at hearings and issue decisions on claims involving disability and Medicare benefits. In some cases, a medical expert is needed to review the medical evidence prior to the hearing and then testify at the hearing. The medical expert may be asked to clarify ambiguities, to resolve contradictory medical evidence, etc. This is not a full-time position, and the medical expert serves under contract, not as an employee of the Office of Hearings and Appeals. Pursuant to that contract, the typical rate of reimbursement is $160.00 for studying the record and testifying at each hearing. Our current medical experts especially enjoy the opportunity to provide an important public service. Please contact Bruce H. Zwecker, Hearing Office Chief Administrative Law Judge, Social Security Administration, Office of Hearings and Appeals, 157 Church St., 22nd Floor, New Haven, CT 06510; telephone (203) 787-7771.

PHYSICIANS WISHING TO PRACTICE IN THE STATE OF CONNECTICUT

GENERAL PRACTICE

Available 30 October 1998. Licensed in Connecticut. Passed National Boards. M.D. at University of Texas, Galveston. Internship at University of Louisville, Kentucky. J.D. at University of Texas, Austin. Have experience in clinical medicine, technical writing and law. Medical work involving administration would be desirable. Please respond to: Lauren O'Neal, M.D., J.D., P.O. Box 293, Litchfield, CT 06759; telephone (210) 824-2915.

Available October 1998. Licensed in Connecticut. M.D. at Universidad Technologica de Technologica de Santiago, Dominican Republic. Internship and residency at Brookdale Hospital, New York. Fellowship at Kings County Hospital/ Long Island College Hospital, New York. Seeking a position in a walk-in, community health or urgent care clinic. Please respond to: Mallick Q. Alam, M.D., 39B Robert Treat Dr., Milford, CT; telephone (203) 882-0638.

INTERNAL MEDICINE

Available July 1999. Licensed in Maryland. Passed National boards. American board eligible. M.D. at Dartmouth Medical School. Internship and residency at Johns Hopkins Bayview Medical Center. Looking to join a group practice in a small to medium sized community. Please respond to: John A. TenBrook, Jr., M.D., 29 Lincoln Woods Way #2C, Perry Hall, MD 21128; telephone (410) 931-3289.

Available January 1999. Licensed in Connecticut. Passed National Boards. American Board certified. M.D. at Tufts University School of Medicine. Internship and residency at the Hospital of St. Raphael. Office based general internist with extensive managed care experience, seeking to join a group or associates practice. Please respond to: Michael F. Collins, M.D., 53 Cotswold Close, Glastonbury, CT 06033; telephone (860) 633-5698.

PRIMARY CARE

Available July 1999. Licensed in Pennsylvania. Passed National boards. American board eligible. M.D. at Government Medical College, India. Internship and residency at State University of New York at Buffalo. Seeking a primary care position in a rural or suburban area. Please respond to: Tasaduq Fazili, M.D., 27-5 Slate Creek Dr., Cheek Towaga, NY 14227; telephone (716) 656-9468.

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The Harvard Medical School and the Beth Israel Deaconess Medical Center, both of Boston, are seeking participants for a genetic study on aging. Subject candidates are individuals 98 years old and older and their living brothers and sisters who are at least 90. Participants do NOT have to live in the Boston area. Participation is voluntary and free of charge. To help us discover information that could lead to a cure for such devastating diseases as Alzheimer's disease and cancer, please refer us to any of your patients who may qualify. Call us toll-free at 1-888-333-6327. Thank you for your assistance.

MARK YOUR CALENDAR

Connecticut State Medical Society

Semi-annual Meeting—House of Delegates

19 November 1998

11:30 a.m.—Registration and Luncheon
12:30 p.m.—Call to Order

Ramada Inn, 275 Research Parkway, Meriden

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HARTFORD, CT 06142-0816

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The Consumer Affairs Division of the Department of Insurance receives, reviews, and responds to complaints and inquiries from state residents concerning insurance related problems. The staff examines each complaint to determine whether statutory requirements and contractual obligations within the commissioner's jurisdiction have been fulfilled. The Consumer Affairs Division coordinates the resources available within the Department to address consumer complaints.

In order for the Division to pursue a formal review of a concern or complaint, the consumer must submit a written explanation to the address listed above with as much pertinent detail as possible. Each written submission to the Consumer Affairs Division will be acknowledged.

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Address: ______________________________________

Phone where the Department can contact you: (_____) ______________________

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Name of Policyholder: ______________________________

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 NOVEMBER 1998 NUMBER 11

scientific:

Robert A. Schwartz, William N. Rezuke, Richard W. Cartun, and Jack Hasson 643 **Case Report: An Autopsy Study of a Rare T-cell Lymphoma Clinically Misdiagnosed as Fulminant Hepatic Disease**

Mark L. Metersky, John Z. Mennone, and Jonathan M. Fine 649 **Factors Inhibiting Use of the Pneumococcal Polysaccharide Vaccine: A Survey of Connecticut Physicians**

Epitomes of Progress

Seth L. Matarasso 619 **Important Advances in Clinical Medicine—Dermatology**

Drug Information Update: Hartford Hospital

Khanh Bui and Richard Quintiliani 665 **Antimicrobial Switch Therapy**

Morbidity and Mortality Weekly Report

669 **Update: Syringe Exchange Programs—United States, 1997**

The Medical Letter

673 **New "Triptans" and Other Drugs for Migraine**

Frank Vinicor 676 **Flu Vaccination Decreases Relative Morbidity Risk for People with Diabetes**

guest editorial:

Morris A. Wessel 677 **The Role of the Primary Pediatrician When a Child Dies**

commentaries:

Maria N. C. Stack 679 **Journal**

Fairfield County Medical Association 680 **Survey of the Retired Fairfield County Physicians**

departments:

Fifty Years Ago

Creighton Barker 681 **World Medical Association Second Annual Assembly, Geneva, Switzerland**

The President's Page

Craig W. Czarsty 685 **In Memoriam: Kathleen McShane, M.D., 1950–1998**

Reflections on Medicine

Robert U. Massey 687 **Twilight of the Heroes?**

Medical News Capsules

Timothy B. Norbeck 689 **This Month's Reading in Review**

Letters to the Editor

James Marshall, Jr. 691 **In Response to "The Ethics of Organ Transplantation"**

Henry N. Blansfield 691 **In Response to Dr. Marshall's Letter**

Charles W. Needham 692 **Simple Truths**

Lee Sataline 692 **In Response to Dr. Koenig's Letter to the Editor "My Daddy, M.D."**

Craig W. Czarsty 692 **HMOs: Managed-access, Not Care**

James M. Dowaliby 693 **In Response to "Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?"**

John P. Welch 693 **In Response to Dr. Dowaliby's Letter**

Jeffrey I. Gorelick 693 **"Welcome to the World of Managed-care " Submitted to the *Danbury News-Times***

general:

695 **Book Review**

699 **Committee Servic**

701 **CSMS Physician F**

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068
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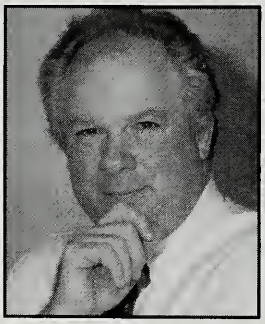

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Case Report: An Autopsy Study of a Rare T-cell Lymphoma Clinically Misdiagnosed as Fulminant Hepatic Disease

ROBERT A. SCHWARTZ, B.A., WILLIAM N. REZUKE, M.D., RICHARD W. CARTUN, Ph.D., AND JACK HASSON, M.D.

ABSTRACT—We describe a case of a 73-year-old male with a rare T-cell lymphoma that presented deceptively as progressive hepatic failure with fever, weight loss, pancytopenia, mental confusion, splenomegaly, and no lymphadenopathy. An alcoholic history supported the diagnosis of cirrhosis, but a liver biopsy was not performed. A bone marrow biopsy was considered unremarkable. Death occurred after a course of four months. Postmortem examination showed hepatic, splenic, lymph node, and marrow infiltration by characteristically sparse, isolated, bizarre, medium-to-large sized neoplastic cells with extensive hepatic centrilobular necrosis, steatosis, and predominant splenic involvement. Immunohistochemical markers indicated a T-cell lymphoma consistent with either an alpha/beta peripheral T-cell lymphoma or a gamma/delta lymphoma. Definitive immunotyping was not available. However, the pathologic features are most consistent with a gamma/delta T-cell lymphoma. This case is an example of a rare, rapidly progressive lymphoma, which is a recognized clinical entity, easily missed, and treatable. Its diagnostic consideration must be explicitly communicated to pathologists, because the isolated or sparse tumor cells in a lymph node, liver, or bone marrow biopsy may easily be mistaken for variants of megakaryocytes or histiocytes.

Introduction

T LYMPHOCYTES mature in an orderly fashion, and undergo sequential gene rearrangements for the unique T-cell receptors (TcR) by which T cells are classified. The genes that code for the TcR undergo sequential gene rearrangements early in T-cell development. There are four TcR genes (alpha, beta, gamma, delta) which code for two types of TcR that exist as heterodimers—the alpha/beta receptor and the gamma/delta receptor. The majority of T cells (98% to 99%) possess the alpha/beta receptor, while the remaining 1% to 2% possess the gamma/delta receptor. The first TcR gene to rearrange is delta, followed by gamma, beta, and alpha. Therefore, the gamma/delta subset represents less mature T lymphocytes as compared to the alpha/beta T cells. However, gamma/delta T cells are fully functional with lymphokine-mediated responses and cytotoxicity, and are not merely immature alpha/beta lymphocytes.[1–2] Gamma/delta T cells typically comprise 2% to 4% of T cells in lymph nodes, 1% to 10% of circulating peripheral blood T lymphocytes, 3% to 5% of medullary thymocytes, and 15% of splenic T cells.

In adults, most T-cell lymphomas exhibit the alpha/beta TcR. A wide variety of T-cell lymphomas have been described and typically present with lymphadenopathy, fever, and weight loss. Liver and spleen involvement are not discovered until the staging evaluation. Recently, a distinct gamma/delta "hepatosplenic" T-cell lymphoma has been recognized as a distinct clinicopathologic entity in the Revised European-American Lymphoma (REAL) classification and is likely the neoplastic counterpart of normal gamma/delta T cells.[2–4] This lymphoma primarily involves the red pulp of the spleen and the hepatic sinusoids without lymphadenopathy, thus mimicking the distribution of normal gamma/delta T cells. Bone marrow

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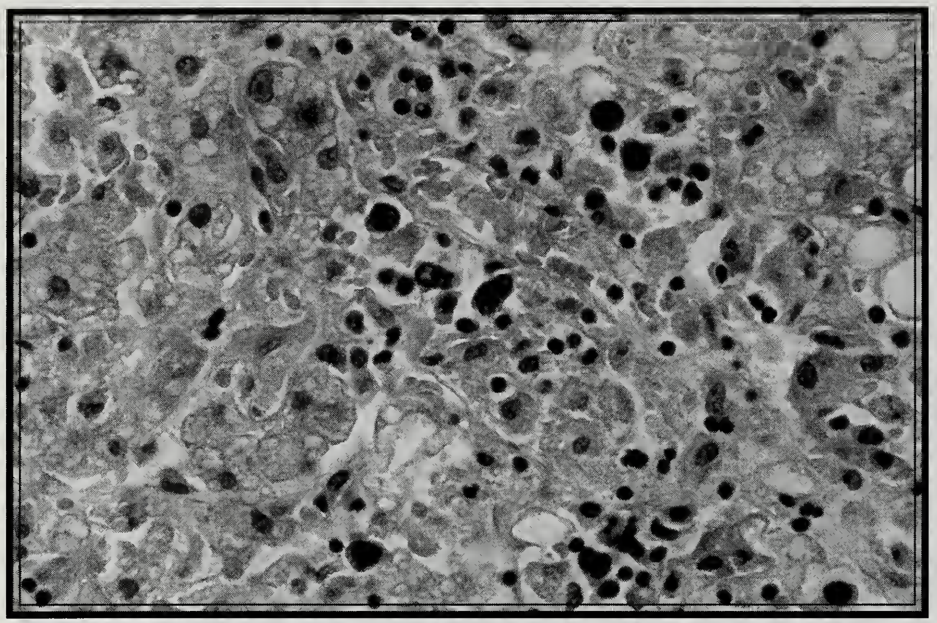

Figure 1.—Liver showing sparse infiltration by large, lymphoma cells. Note extensive microvesicular fatty change (H&E, 20x).

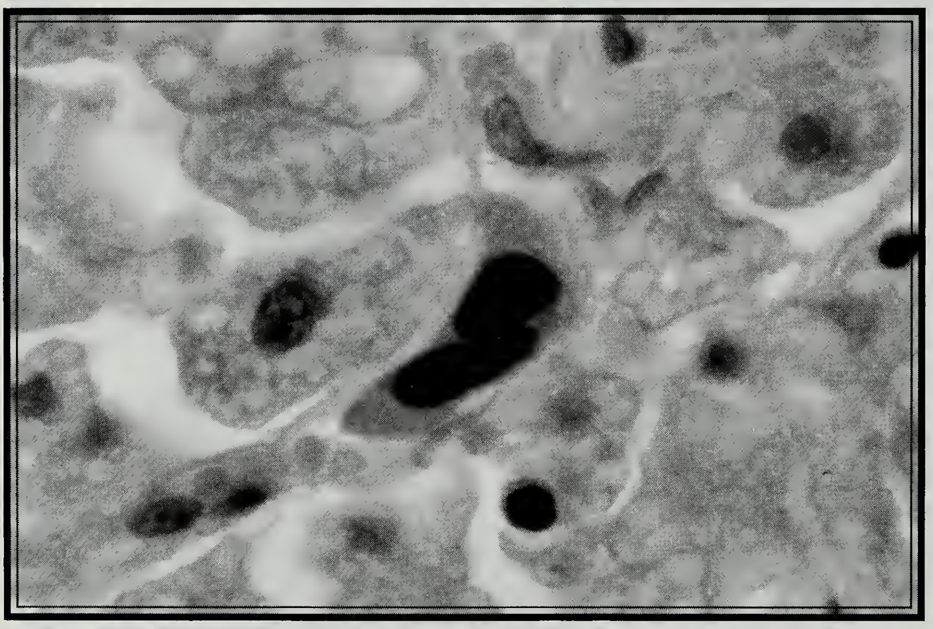

Figure 2.—High-power view of a bizarre, atypical lymphoma cell in an hepatic sinusoid (note adjacent red cells). Extensive hepatocellular fatty change is also present (H&E, 100x—oil immersion).

involvement is frequent and is associated with varying degrees of pancytopenia. The identification of this lymphoma in biopsied tissue may be demanding because of the tendency of the tumor cells to be distributed as isolated single cells, resembling variants of megakaryocytes, rather than as obvious sheets of neoplastic cells. This disease is aggressive and the median survival period is less than three years from the time of diagnosis.[2–8] We describe a case of probable hepatosplenic gamma/delta T-cell lymphoma which was diagnosed at autopsy.

Case Report

Clinical history.—This was a 73-year-old white male who became weak, anorectic, and confused toward the end of August 1996. His past history was significant for coronary artery disease, and that he customarily had drunk three to four beers per day for many years.

The patient was hospitalized from 31 August 1996 through 12 September 1996 with a presumptive diagnosis of a "viral infection." Temperature on admission was 38.2° C. Bone marrow biopsy was performed because of mild pancytopenia; no hematological malignancy was identified. Abdominal ultrasound and computed tomographic scan (CT) revealed an enlarged liver, and he was discharged with a clinical diagnosis of Laennec's cirrhosis and hepatic encephalopathy. Readmission on 23 November 1996 was necessitated by abnormal liver function tests, hepatosplenomegaly, neutropenia, thrombocytopenia, encephalopathy, weight loss, and dehydration. He was afebrile with temperatures varying between 35° C and 36.6° C. At that time, laboratory values showed mild pancytopenia, mildly elevated liver enzymes, and a slightly elevated ammonia level. He was rehydrated, started on lactulose and protein restriction, and discharged on 30 November 1996.

The patient was referred to our hospital on 10 December 1996, was again hospitalized complaining of malaise, anorexia, and physical exhaustion. He denied nausea, vomiting, jaundice, bruising, or hematochezia, but did have diarrhea since beginning the lactulose therapy. Weight loss of 25 lbs. (220 lbs to 195 lbs.) was noted since he was first seen in August. On physical examination at the time of admission he had a low-grade fever (38°C), orthostatic hypotension, slightly icteric sclera, a mildly tender right upper quadrant with no palpable masses, and a questionable abdominal fluid wave. No asterixis, palmar erythema, mucus membrane petechiae, or spider telangiectasias were identified. At admission laboratory values showed the following: blood urea nitrogen, 60 mg/dL; creatinine, 2.8 mg/dL; aspartate aminotransferase, 223 U/L; alanine aminotransferase, 202 U/L; alkaline phosphatase, 339 U/L; total bilirubin, 5.4 mg/dL; direct bilirubin, 3.2 mg/dL; and lactic dehydrogenase, 596 U/L. Of note was a normal ammonia level at 39 μmol/L. Peripheral blood values were also abnormal with a white blood cell count of 2.1 x 10^9/L (differential: neutrophils 49.7%, lymphocytes 39.1%, monocytes 9.6%, eosinophils 0.1%, basophils 1.5%), hemoglobin of 12.8 g/dL, hematocrit of 37.6%, platelet count of 31 x 10^9/L with elevated prothrombin time of 38.9 (11.0-13.0), partial thromboplastin time of 73.9 (24.0-32.0), and an international normalized ratio of 12.26 (0.7-1.25). No abnormal lymphocytes were noted on routine peripheral blood smear.

This hospital course was marked by hypotension (systolic blood pressure—80-90mm Hg), altered electrolyte and fluid balances, and oliguria. One day after admission, his temperature spiked to 39°C, white blood cell count dropped to 1.1 x 10^9/L, and platelet count dropped to 18 x 10^9/L. Paracentesis revealed no ascitic fluid. Tachypnea and bradycardia developed, and the patient expired at 5:00 A.M, 12 December 1996.

Autopsy findings.—Grossly, the autopsy findings were significant for an enlarged, fatty liver weighing 2,750 g with no evidence of cirrhosis. The gallbladder was unremarkable, the portal vein was patent, and the bile duct system was patent to the ampulla of Vater. The spleen was enlarged and weighed 800 g. The lungs were hyperemic and heavy (1,450 g), but normally crepitant with no palpable areas of consolidation. The right and left main coronary arteries showed significant atherosclerotic stenosis (greater than 75% stenosis), and there were subendocardial scars. The heart showed no evidence of old or recent infarcts. The kidneys were grossly unremarkable. There was no lymphadenopathy. There were bilateral pleural effusions of clear fluid with 300cc and 200cc in the right and left pleural cavities, respectively. A peritoneal effusion of 1200cc was also noted.

Microscopically, a lymphomatous infiltrate was identified involving the spleen, liver, lymph nodes, and bone marrow. The cells were large with scant cytoplasm, and had large, universally pleomorphi,c homogeneous, hyperchromatic nuclei without nucleoli or granular chromatin markings. The staining of the nucleus had an artificial quality of an ink-drop rather than that of nucleoplasm. Occasional nuclei were huge with a complex shape. The other characteristic microscopic feature was the distribution of the neoplastic cells as single cells scattered throughout the involved tissues, without forming sheets of cells so characteristic of most non-Hodgkins lymphomas. These individual cells were found in the liver sinusoids and portal areas (Figs. 1 and 2), in the bone marrow where these cells could easily be mistaken for atypical megakaryocytes, and in the spleen where they resembled malignant histiocytes. Review of the original bone marrow biopsy did indeed reveal the characteristically isolated neoplastic cells, which had been misread as atypical megakaryocytes. Scattered single cells were also found in sinusoids and lymphoid tissue of the lymph nodes, along with sinusoidal macrophages. The liver showed fine microvesicular fatty changes and focal centrilobular necrosis, and a mild increase in iron stores, but no evidence of increased fibrosis or Mallory bodies to suggest an alcoholic etiology. The neoplastic cells were often associated with aggregates of mature-looking lymphocytes. The heart and lungs showed microscopic foci of tumor infiltration. The most densely infiltrated organ was the spleen, but the cells were still characteristically individually scattered throughout the parenchyma.

Immunophenotypic Analysis

Immunohistochemical studies were performed on paraffin-embedded autopsy material with a panel of monoclonal antibodies and the Avidin-Biotin-Complex (ABC) technique, as previously described.[9] The tumor cells in the spleen, bone marrow, and liver were positive for CD45RO (UCHL-1), a T-cell marker. However, the tumor cells were negative for CD3, a pan-T-cell marker. Other T-cell subset markers and natural killer (NK) markers could not be evaluated due to the lack of fresh tissue. The B-cell markers CD20 (L26) and CD30 (Ki-1) were negative, ruling out the possibility of anaplastic large cell lymphoma (ALCL). Histiocytic markers KP-1, HAM-56, and lysozyme were negative in malignant cells, and positive in numerous benign histiocytes, thus eliminating malignant histiocytosis from the differential diagnosis. Gene rearrangement studies were unsuccessful again due to lack of fresh tissue. In short, these findings were consistent with a diagnosis of T-cell lymphoma.

Discussion

The T-cell non-Hodgkins lymphomas are a heterogeneous group of malignancies with extensive variation in clinicopathologic features. The case described is a T-cell non-Hodgkins lymphoma involving the spleen, liver, lymph nodes, and marrow, and is consistent with a hepatosplenic gamma/delta T-cell lymphoma (REAL classification).[2] However, we could not prove this characterization without fresh tissue to determine gamma/delta gene rearrangement. Hepatosplenic gamma/delta lymphoma is a distinct clinicopathological entity which, prior to the advent of reliable immunophenotypic and molecular genetic analysis, was called by various names including malignant histiocytosis, medullary reticulosis, and anaplastic large-cell lymphoma. In 1982, Colby and LaBrecque described four cases of "malignant histiocytosis" presenting as fulminant hepatic disease.[10] All four cases were characterized by sparse malignant infiltration of the liver and spleen, and the extent of the liver infiltrate as judged histologically was mild compared with the severity of the clinical illness.[10]

The present case closely parallels Colby's and LaBrecques's cases both in its presentation as progressive liver disease, and by the paucity of neoplastic cells in the liver. In the case described, the degree of hepatic infiltration is discordant with the degree of liver dysfunction and hepatocyte necrosis. Previous studies have indicated varying levels of cytotoxic granule-associated proteins (TIA-1), perforin, and extensive NK-like cytotoxic effects in activated gamma/delta T cells.[2,6,11] This remains a plausible explanation for the degree of hepatocyte destruction in this case.

Varying degrees of peripheral blood cytopenias are associated with hepatosplenic gamma/delta T-cell lymphoma, and the level of thrombocytopenia has been reported to parallel disease progression.[2] The cytopenias are probably due in part to hypersplenism as suggested in this case by megakaryocytic hyperplasia of the bone marrow. However, platelet counts often do not fully rebound following splenectomy[2,4] and thus additional mechanisms, such as tumoral bone marrow infiltration and humoral factors, may account for these peripheral blood abnormalities. Specifically, hematopoietic suppression has been described in several cytotoxic T-cell leukemias, and in a single case of cutaneous gamma/delta T-cell lymphoma showing high levels of interferon-gamma.[2,13–16]

Immunophenotypically, hepatosplenic gamma/delta T-cell lymphomas have been reported as CD2+, CD3+, CD4-, CD5+/-, CD7+/-, CD8+/-, CD56+/-, CD45RO (UCHL-1)+, and TcR(gamma/delta)+.[2–9] This case was CD45RO+, but CD3-, a finding which may be explained by development of a clonal T-cell population prior to the evolutionary expression of CD3, or, more likely by a mutation effecting CD3 gene expression. Aberrant loss of pan T-cell antigens is a frequent finding in T-cell non-Hodgkins lymphoma. One other CD3- case of gamma/delta hepatosplenic T-cell lymphoma has been reported.[5,12] Reliance in this case on paraffin-embedded, formalin-fixed autopsy material for immunohistochemical study limits the ability to completely and accurately characterize this case. Thus, the clinical and pathological features are most consistent with a gamma/delta hepatosplenic T-cell lymphoma, but conclusive evidence of the gamma/delta phenotype is best demonstrated when fresh tissue is available for immunophenotypic analysis.

Hepatosplenic gamma/delta T-cell lymphoma is an aggressive and potentially fatal malignant neoplasm necessitating rapid diagnosis and treatment. The disease is often difficult to diagnose clinically, due to its relatively nonspecific presentation and extreme rarity. Potentially diagnostic procedures such as liver and bone marrow biopsies may be falsely reported as negative, as occurred in this case, when the lymphomatous infiltrate is sparse, and can easily be mistaken for hematopoietic precursors including megakaryocytes. Also, flow cytometry of the bone marrow can aid in diagnosis of these cases. Therefore, hepatosplenic gamma/delta T-cell lymphoma should be considered in the differential diagnosis in any patient presenting with unexplained liver disease, peripheral blood cytopenias, and splenomegaly.

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Factors Inhibiting Use of the Pneumococcal Polysaccharide Vaccine: A Survey of Connecticut Physicians

MARK L. METERSKY, M.D., JOHN Z. MENNONE, M.P.H.,
AND JONATHAN M. FINE, M.D.

ABSTRACT—*Background.* The pneumococcal polysaccharide vaccine (PPV) is effective in preventing invasive pneumococcal disease, but remains underutilized. Prior surveys of physicians revealed concern regarding the safety and efficacy of the vaccine, but there has been little information published in the last 10 years that sheds light on why the vaccine remains underutilized. Although there is currently emphasis on providing PPV to hospitalized patients, there is even less known about what factors prevent PPV use in the hospital setting and chronic care setting. We performed a survey of physicians in Connecticut to determine what factors prevent utilization of the vaccine in three patient care settings.

***Methods.*—A survey of internists and family practitioners in Connecticut that ascertained their frequency of utilization of PPV and what factors inhibited utilization of PPV.**

***Results.*—Three hundred ninety-seven responses are included in the analysis. Forgetting to administer the vaccine (59% of respondents) and patient refusal (55% of respondents) were the factors most frequently noted as being important in preventing vaccination in the outpatient setting. In the inpatient and chronic care settings, difficulty in determining the patient's vaccine status was also noted. Concerns regarding the efficacy or safety of the vaccine did not seem to be important. The factor that correlated most closely with the respondents' reported frequency of vaccine use was forgetting to vaccinate.**

***Conclusions.*—Physicians, although accepting the efficacy of PPV, are inhibited from its more frequent use by several factors.**

PNEUMOCOCCAL disease is estimated to result in approximately 40,000 deaths per year in the United States.[1] Recent increases in the prevalence of penicillin-resistant *Streptococcus pneumoniae* further increase the difficulty in treating this common pathogen. The pneumococcal polysaccharide vaccine (PPV) has been available since 1977, initially as a 14-valent vaccine and then as a 23-valent vaccine beginning in 1983. For most patient populations, it is generally accepted to be approximately 60% effective in preventing invasive pneumococcal disease, the form of disease associated with the highest mortality rate.[2] The PPV is recommended for all individuals who are at high risk from pneumococcal disease, including those 65 years of age and above, and younger individuals with certain chronic diseases and immunodeficiencies.[2]

Despite its availability for 20 years, PPV is highly underutilized. The 1995 Behavioral Risk Factors Surveillance System data revealed that only 37% of respondents age 65 and older had ever received PPV.[1] This is in marked contrast to influenza vaccine, which 59% of the same respondents had received during the previous 12 months.[1] Accordingly, a component of the ongoing Healthy People 2000 public health initiative is an effort to increase the cumulative PPV vaccination rate of those 65 years of age and older to 60% by the year 2000.[3] Addressing missed

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opportunities for vaccination of patients in doctors' offices, hospitals, and chronic care facilities has been widely proposed as an important approach for achieving this goal.[4]

Numerous strategies have been shown effectively to increase the delivery of vaccines to adults. These include chart reminders,[5] outpatient-based standing orders,[6] and programs facilitating vaccination at hospital discharge.[7] Almost without exception, when such strategies are employed, vaccination rates increase markedly.[4] Clearly, the lack of an organized approach to vaccine delivery plays an important role in its underutilization. Nonetheless, this knowledge has not resulted in a large increase in PPV use, presumably because such measures have not been widely adopted. The continuing underutilization of PPV and the wide disparity between influenza and PPV vaccination rates suggest that other reasons may be operating.

Although few data have been published recently explaining why physicians do not use PPV more frequently, some proposed reasons include inadequate reimbursement for vaccination resulting in a financial disincentive for providers, fear of side effects on the part of both providers and recipients, difficulty in determining if the patient had already received the vaccine, and doubt among providers about the efficacy of PPV.[4] In the 1980s, physician surveys highlighted concerns regarding the efficacy and safety of PPV. In a survey of physicians performed by the Centers for Disease Control in 1980, concerns regarding the safety of the vaccine or patient refusal were rarely cited as important issues preventing vaccination.[8] However, recommended indications for the vaccine were only agreed with by 60% to 70% of responding physicians. The design of the study precluded determining whether this was due to lack of knowledge about the vaccine or disagreement with the recommendations. A survey of 251 physicians in Tennessee in 1981 found that 85% of the respondents thought that PPV had been proven effective but only 39% were convinced of the safety of the vaccine.[9]

These results contrast with those obtained by Williams in a survey of physicians in Hawaii performed in 1988.[10] Only 62% of physicians thought that the influenza and pneumococcal vaccines were effective. Not surprisingly, given the skepticism regarding vaccine efficacy, only 37% always recommended PPV to their patients who had indications for the vaccine.

While there is no way to ascertain definitively the reasons for the lower perceived efficacy of PPV in the 1988 survey when compared to the 1981 survey, two studies published in the interim called into question the efficacy of PPV in some of the populations for whom it is recommended.[11,12] More recently, there has been further evidence that studies failing to reveal a benefit of PPV may drastically affect PPV utilization. In 1995, a Swedish study failed to show a benefit of PPV in preventing pneumococcal pneumonia.[13] During the two years following this study, PPV utilization in Sweden fell by approximately 50% despite suggestions that the study was significantly underpowered.[14]

There have been few data published recently that determine whether physicians in the United States still withhold vaccination due to concerns regarding its efficacy. In addition, although physicians have been urged to increase the use of PPV in nursing homes and acute care hospitals, even less is known about the factors preventing utilization in these settings. Such information might provide some insight as to why PPV remains underutilized by physicians, despite widespread knowledge of interventions that effectively increase vaccination rates. Because of the limited data regarding these issues we conducted a survey of internists and family practitioners in Connecticut regarding issues that may prevent PPV use.

Methods

A questionnaire was developed to obtain basic demographic information as well as to determine the importance of various factors in influencing the use of PPV by the respondent. A mailing list of all internists and family practitioners with a Connecticut license was obtained from the Connecticut State Medical Board. This list encompassed 3,787 physicians, of whom 75% were internists and 25% family medicine practitioners. Those whose mailing addresses were not in Connecticut were excluded, because of the likelihood that they were no longer practicing in Connecticut, leaving 3,284 who were sent the survey. Two mailings were made to maximize response rate. Because the survey was filled out anonymously, each mailing went to the total group. Included in each mailing were the Centers for Disease Control recommendations for the use of the vaccine, so that the respondent could refer to them when answering the questionnaire.

Results for each question are reported as percentages as the response rate for the individual questions varied becasue of missing answers. The χ^2 test was used to determine the relationship between the factors that might prevent vaccination and the respondents' reported vaccination rates, as well as to determine whether there were differences between responses to the first and second mailing. Significance was accepted at $P<0.05$. Values are reported as mean ± one standard deviation when applicable. The study was approved by the Institutional Review Board of the University of Connecticut Health Center.

Results

Three hundred thirty-nine surveys were returned after the first mailing and 82 after the second mailing, for a total response rate of 421 (13%). None of the responses to the second mailing shared the same zip code, sex, and age with

Table 1.—Physicians' Estimated Rate of Pneumococcal Polysaccharide Vaccination of their Eligible Patients.

Percent of eligible patients vaccinated	**Percent of physicians vaccinating at each rate** **Outpatient**	**Inpatient**	**Chronic care**
0-20%	30%	66%	22%
21-40%	14%	7%	7%
41-60%	15%	5%	10%
61-80%	19%	7%	16%
81-100%	22%	14%	46%

a response from the first mailing, so it is unlikely that there were any duplicate responses. Twenty-four respondents indicated that they were not involved in patient care; they were excluded, leaving 397 responses included in the analysis. Seventy-five percent of responding physicians were male, and 25% were female, the mean age was 48 ± 12 years. Seventy-nine percent of respondents identified themselves as internists, of whom 133 (34%) were board certified in one of the subspecialties of internal medicine. Eighteen percent identified themselves as practicing family medicine and 3% identified other types of practice. No noteworthy relationships were found when the results were analyzed according to year of medical school graduation or type of practice (academic *vs* non-academic); accordingly these analyses are not presented. When the responses to the first and second mailings were compared, the response to only one of the 29 reported variables was significantly different.

The respondents' estimates of the frequency with which they administered the vaccine to their patients in various settings are shown in Table 1. Vaccination was most frequently performed in the chronic care setting and least frequently in acute care hospitals. Outpatients were vaccinated at an intermediate rate.

Table 2 shows the respondents' perceptions regarding factors that may prevent utilization of PPV. The respondents could characterize each of the factors as either *very important, moderately important, slightly important,* or *not important*. In order to simplify data presentation, we chose to combine the first two and latter two options. The responding physicians viewed patients' refusal of the vaccine and their own forgetting to offer the vaccine as the two most important factors that prevented them from vaccinating their patients in the outpatient setting. Another important factor was difficulty in determining the patients' vaccine status. Most respondents appeared to be convinced of the efficacy and safety of the vaccine.

Physicians noted that difficulty in determining a patient's vaccine status was an even greater deterrent to vaccination in the hospital and chronic care facility than in the outpatient setting. Patient refusal of the vaccine was thought to be an important issue in these settings as well. Others simply noted that they do not vaccinate in the acute care setting, although few appeared concerned about the efficacy in hospitalized patients.

We also attempted to determine to what extent each of the potential reasons preventing vaccination correlated with the respondents' estimated vaccination rates (Table 3). Physicians who thought that forgetting to vaccinate was either a very or moderately important factor vaccinated significantly fewer patients in all three care settings than physicians who thought it was a slightly important or unimportant factor. In contrast, although difficulty determining if the patient had received the vaccine was thought to be an important issue preventing vaccination by a large percentage of respondents, their vaccine administration rates were not significantly less than those who did not find it to be an important factor preventing vaccination.

Discussion

Given the controversy in the literature regarding the efficacy of PPV,[4] we were concerned that its underutilization might be related to a widespread belief among physicians that the vaccine is not efficacious. Such a perception, if present, would suggest that current efforts to increase PPV usage are likely to meet resistance as physicians may defy efforts to change their practice unless they agree that the change will result in improved care.[15] Fortunately, the results of this survey suggest that most physicians are convinced of the efficacy of the PPV.

Our survey had a low response rate of only 13%, leading to a concern that nonresponse bias may be skewing our results. Perhaps because of the increasing pressures upon physicians recently, low response rates to mail surveys have been noted by other investigators.[16,17] Generally, this

Table 2.—Reported Importance of Factors that can Pprevent Vaccination with the Pneumococcal Polyvalent Vaccine.

Factor preventing vaccination	Outpatient		Inpatient		Chronic care	
	Very/moderately important	Slightly/not important	Very/moderately important	Slightly/not important	Very moderately important	Slightly/not important
Forget to consider vaccinating, but would have vaccinated if I'd thought of it.	59%	41%	60%	40%	42%	58%
Do not think 23-valent pneumococcal vaccine is efficacious.	12%	88%	8%	92%	8%	92%
Inadequate reimbursement.	13%	87%	8%	92%	8%	92%
Patient refuses.	55%	45%	40%	60%	44%	56%
Difficulty in determining if the patient had already received the vaccination.	42%	58%	57%	43%	56%	44%
As a consultant, I consider vaccination to be the responsibility of the primary care physician.	42%	58%	35%	65%	30%	70%
Do not vaccinate in this setting.	11%	89%	41%	59%	9%	91%
Concern regarding side-effects	7%	93%	10%	90%	4%	96%

has not seemed to affect the validity of the surveys in question.[16,18,19] The striking similarity between the results from our first and second mailings suggest that non-response bias may not be skewing our results greatly, although this cannot be stated with certainty. Given the overwhelming percentage of physicians who believed that PPV is safe and effective, it seems unlikely that non-response bias explains this important finding.

It is well known that surveys of physician practices generally result in an overestimation of the frequency of vaccine utilization. There is no reason to believe the same issue did not affect our results. However, the results showed markedly different estimated vaccination rates for each of the patient care settings, with the lowest rates reported in the acute care setting. This is consistent with reports that very few hospitalized patients are vaccinated.[20] The highest rates were reported in the chronic care setting. This is not surprising, as approximately 40% of chronic care facilities in Connecticut have standing orders for PPV administration (unpublished results, Connecticut Pneumonia and Influenza Coalition). Although the respondents' absolute reported vaccination rates cannot be accepted as valid, the rates reported in our survey are in general agreement with published data and therefore appear to be useful for comparison purposes.

In this survey, physicians most frequently reported that simply forgetting to consider the vaccination was a barrier to vaccination. Indeed, this issue correlated highly with the reported vaccination rates among the responding physicians. This result confirms the necessity of an organized approach to vaccination. Responding physicians also frequently felt that difficulty in determining whether the patient had previously received the vaccine was an important issue preventing vaccination, although this issue did not actually seem to affect estimated vaccination rates. Although recommendations suggest vaccinating despite an unknown vaccine status, physicians may be reluctant to do so because of concern for side effects or fear of being

Table 3.—χ^2 Analysis* of Reported Importance of Issues Affecting Vaccination† *vs* Reported Rate of Vaccination of Eligible Patients.‡

Factor preventing vaccination	Outpatient *P*-value	Inpatient *P*-value	Chronic care *P*-value
Forget to consider vaccinating, but would have vaccinated if I'd thought of it.	0.0004	0.004	0.00005
Do not think 23-valent pneumococcal vaccine is efficacious.	NS	NS	NS
Inadequate reimbursement.	NS	NS	NS
Patient refuses.	NS	NS	NS
Difficulty in determining if the patient had already received the vaccination.	NS (0.06)	NS	NS
As a consultant, I consider vaccination to be the responsibility of the primary care physician.	0.02	NS	NS
Do not vaccinate in this setting.	<0.00001	<0.00001	0.00003
Concern regarding side-effects.	NS	NS	NS

*This analysis determines the relationship between a factor that may prevent vaccination and the reported vaccination rate. A *P* value ≤0.05 means that those who reported the factor as very or moderately important reported vaccinating a significantly lower percent of patients than those who reported that the factor was slightly or not important. A *P* value of not significant (NS) means that the importance of the factor did not have a significant association with the percentage of patients vaccinated.

†Variable Categories: very or moderately important versus slightly or not important

‡Variable Categories: 0-20%; 21-40%; 41-60%; 61-80%; 81-100%

denied reimbursement for patients who had previously been vaccinated. Difficulty in determining patients' vaccine status was a more important issue in the acute care and chronic care settings than the outpatient setting. Interventions to improve communication regarding vaccine status might be a useful component of efforts to increase vaccine usage. For example, adding vaccination status to the standard interagency patient transfer form might address this issue.

The respondents frequently reported that patient refusal was a factor preventing them from using the vaccine. There are two ways of interpreting this result. The first is the possibility that patients truly are less accepting of PPV than is generally realized. The second possibility is that physicians do not strongly advocate the vaccine, leading to reluctance of patients to undergo vaccination. Most physicians do not have the opportunity to spend an extended amount of time convincing a reluctant patient to accept vaccination and patients are less familiar with PPV than the influenza vaccine.[21] Efforts by organizations that promote and run outpatient vaccine clinics have been generally directed toward influenza vaccine and not PPV. Among Connecticut public health districts that promoted and offered fall vaccine clinics in 1996, only about one third offered PPV (unpublished data, Connecticut Association for Directors of Health). The Health Care Financing Administration, through the state Quality Improvement Organizations, has also concentrated much more on promoting influenza vaccination than PPV. Only about 20% of adult immunization related quality improvement projects by these organizations focus on PPV.[22] This lack of effort by the public health community may translate into less knowledge and acceptance of PPV by patients.

The findings regarding vaccination in the acute care setting differed in one important way from those in the outpatient setting. A higher percentage of physicians seemed simply not to consider immunizing in the acute care setting, despite evidence that such patients are at the highest risk of subsequent morbidity from pneumonia.[4] As would be expected, this response correlated highly with respondents' reported vaccination rates in the acute care setting (Table 3).

The results of this survey provide several insights into why PPV utilization remains low. Physicians clearly forget to vaccinate patients due to lack of an organized approach to vaccination, and this factor correlates highly with the responding physician's estimated vaccine administration rate. Physicians also perceive a resistance from patients when they do attempt to utilize the vaccine. More extensive efforts on the part of public health organizations to promote the use of PPV, similar to the efforts with the influenza vaccination, are likely to influence both of these factors.

Although public health organizations may facilitate vaccination, individual physicians in their offices must play the leading role. Increased utilization of PPV may be achieved more easily through the routine use of chart stickers and computerized reminders. Another method that has been successful is placing the responsibility for vaccination in the hands of a nurse, who may be less busy than the physician. Setting aside specific times for vaccine clinics can prevent the patient flow difficulties that vaccine efforts may otherwise produce.

We now know that although most internists and family physicians in Connecticut remain convinced of the efficacy of PPV, physician inattention is in large part responsible for the low vaccination rate. The greater than 90% delivery rate of childhood immunizations[23] proves that we are capable of doing better. It is time to try.

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Important Advances in Clinical Medicine

Dermatology

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The Council on Scientific Affairs of the California Medical Association presents the following epitomes of progress in dermatology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, as to both scientific fact and important clinical significance. The items are presented in simple epitome, and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, researchers, and scholars to stay abreast of these items of progress in dermatology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Dermatology of the California Medical Association, and the summaries were prepared under the direction of Dr. Matarasso and the Panel.

Psoriasis Therapy Update

THE therapy of psoriasis can be subdivided into three categories: topical therapies, phototherapies, and systemic therapies.

Topical Therapies

The history of topical steroid therapy in dermatology has featured the synthesis of increasingly potent preparations. However, local side effects (steroid atrophy, folliculitis, opportunistic skin infections, etc.) and the potential for absorption and suppression of the hypothalamic-pituitary-adrenal axis limit their use. In addition, loss of efficacy over time can occur. Thus, nonsteroidal alternatives for the topical treatment of psoriasis are desirable. Recently, a vitamin D3 analog, calcipotriene, has been approved for the topical treatment of psoriasis. Calcipotriene works by decreasing epidermal proliferation and enhancing differentiation; it may have immunomodulatory properties as well. The potency of calcipotriene ointment approximates that of topical fluocinonide without the potential hazards of topical steroid treatment or the problem of tachyphylaxis. Unfortunately, compared to topical steroids, its onset of action is rather slow (four to six weeks) and cutaneous irritation may occur. Thus, initial combination treatment with a topical steroid and calcipotriene allows for more rapid onset of improvement with less irritation. Later, the patient may be switched to calcipotriene treatment alone. Other vitamin D3 analogs are in clinical trials, as are topical tacrolimus (an immunosuppressant drug) and various ascomycin derivatives (which have antiinflammatory activities). Tazarotene, a topical retinoid, also has been approved for the topical treatment of psoriasis, although cutaneous irritation is quite common, and the marketed preparation is extremely expensive.

Phototherapies

Natural sunlight (heliotherapy) is a cheap and effective way of treating psoriasis, and most patients notice remission during the summer. Artificial sources of ultraviolet B irradiation (UVB) are also helpful. Patients can purchase a UVB light unit for home use, but the frequency and intensity of therapy should be monitored by the physician at least quarterly. Narrow-band UVB is a new form of UVB therapy that may offer some advantages over broad-band WB treatment. Photochemotherapy (PUVA), a com-

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bination of oral 8-methoxypsoralen followed by ultraviolet A (UVA) exposure, is highly effective in the treatment of psoriasis. However, cutaneous carcinogenesis is a major concern after long term use. With any form of phototherapy, a sunscreen should be applied to uninvolved areas to decrease the risk of skin cancer.

Systemic Therapies

Methotrexate (an antimitotic and antiinflammatory agent) and acetretin (an oral retinoid) are the most commonly used systemic therapies for psoriasis. Both drugs have important short- and long-term side effects and should be prescribed only by physicians familiar with their use. Recent studies have suggested that gastrointestinal side effects from methotrexate may be alleviated by ingestion of folic acid. Although periodic liver function tests are routinely performed on patients undergoing methotrexate therapy, the results may remain normal in the face of underlying hepatic damage, which can be reliably assessed only by liver biopsy. Acetretin and its parent drug, etretinate, are known teratogens. Female patients receiving acetretin should use two forms of contraception during the treatment period and for at least three years thereafter. Hypertryglyceridemia is common, especially in older patients. Myriad other adverse effects associated with acetretin therapy should be reviewed with the patient by the prescribing physician. Cyclosporine is effective in the treatment of psoriasis, but hypertension and decreased renal function are common sequelae; thus, only patients with severe disease warrant its administration. As with methotrexate, a prompt and often severe rebound can occur after treatment is discontinued. Systemic administration of corticosteroids should never be used in treatment, except in the rare patient with severe, life-threatening psoriasis.

Combination Therapies

Combination therapy permits the use of lower doses of the individual components, thus decreasing their individual toxicities. Combination therapy may include the concurrent use of a topical preparation, such as calcipotriene ointment, with either a phototherapy or systemic therapy, or the use of a systemic agent, such as acetretin, with a phototherapy. For most patients with moderate to severe psoriasis, combination therapy is more effective and less hazardous than monotherapy.

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The Pathogenesis of Kaposi's Sarcoma

KAPOSI'S sarcoma (KS) has received immense attention since 1981 when it was first recognized as a major manifestation of the Acquired Immune Deficiency Syndrome (AIDS). Four forms have been described: an indolent, endemic form seen most commonly in older Mediterranean men; a second form seen in tropical Africa commonly affecting children; an "iatrogenic" form that occurs in individuals receiving immunosuppressive therapy such as organ transplant recipients; and the form associated with HIV infection. Skin lesions are similar in all groups and all appear similar histologically. Vascular endothelial cells are thought to be the cell of origin of KS on the basis of morphology, presence of vascular spaces, ultrastructural appearance, and the expression of various endothelial markers.

The true nature of KS is a subject of intense study. Whether KS is a clonally derived malignancy or a proliferation of spindle cells in response to local cytokines has been a subject of controversy. High local levels of cytokines including interleukin 6 (IL-6), basic fibroblast growth factor (bFGF), tumor necrosis factor α (TNF-α), interferon γ and vascular endothelial growth factor (vEGF) have been shown to be present in KS lesions. Interleukin-6 is produced by KS spindle cells themselves and exogenous IL-6 has been shown to enhance the proliferation of KS cells in culture. Other features that favor a proliferative rather than truly neoplastic process include the fact that there are often many lesions that develop simultaneously without a characteristic primary lesion and the absence of a tendency to spread regionally to local lymph nodes. Furthermore, lesions often resolve when the patient's immunocompetence is reconstituted. On the other hand, a recent article demonstrated clonality of KS lesions with identical genetic sequences in different KS lesions in the same patient. This does not necessarily prove that KS develops from a primary lesion and spreads throughout the body, however.

An infectious etiology for KS has been sought for over three decades. In 1994 Chang and Moore discovered herpes-like DNA sequences in KS tissues from patients with AIDS. These sequences were not identified in tissues from normal hosts, lymph nodes, peripheral lymphocytes infected with Epstein Barr virus (EBV), DNA extracted from other vascular tumors, or other tissues involved with

AIDS opportunistic infections. These DNA sequences are partially homologous to gene segments of γ-herpesvirinae such as *Herpesvirus saimiri* and EBV. This novel herpesvirus associated with KS was thus classified as a γ-herpesvirinae and called Kaposi's sarcoma-associated herpesvirus (KSHV) or Human Herpesvirus-8 (HHV-8).

Since HHV-8 was discovered, researchers have sought to prove that the virus is truly the cause of KS and not simply a cofactor. Three bodies of evidence suggest causality. First, HHV-8 is present in all types of KS and is present in virtually all samples tested to date. Second, serologic studies show that the prevalence of HHV-8 infection in various geographic and risk-group populations parallels the incidence of KS in these populations. Third, both polymerase chain reaction (PCR) based detection of HHV-8 DNA in peripheral blood and antibody seroconversion studies show that HHV-8 infection occurs before the development of KS and is highly predictive of its development.

Current research aims to define the role of HHV-8 in initiating the pathogenesis of KS lesions. Several potential oncogenes have been identified that allow the virus to avoid antiviral responses such as cell-cycle arrest, apoptosis and enhanced cell-mediated immunity, any of which could lead to abnormal cell proliferation.

The current treatment options for all forms of widespread or systemic KS include cytotoxic drugs (bleomycin, vinca-alkaloids, anthracyclines and taxol), systemic interferon and radiotherapy. Overall, conventional chemotherapy and radiation are only partially effective and have significant adverse effects. Novel approaches that take into account the recent discoveries of molecular factors that produce KS lesions are already in development. Drugs that diminish angiogenesis in KS have been shown to be at least partially effective in preliminary studies. For example, thalidomide, a drug that blocks angiogenesis in developing limb buds, has been reported to induce regression of KS lesions in some patients. Antiviral agents that with activity against HHV-8 such as foscarnet, ganciclovir and acyclovir are also currently being investigated and preliminary results indicate that foscarnet may cause remission of some KS lesions. Furthermore, KS lesions in HIV-positive individuals often resolve after initiation of treatment with Highly Active Antiretroviral Therapy (HAART) that includes 2 nucleoside reverse transcriptase inhibitors and a protease inhibitor. Although HAART may have some antiviral activity against HHV-8, it is likely that the effect is related to improvement in the patient's immunity. This is analogous to the regression seen in KS that develops in transplant patients when immunosuppression is stopped.

Thus, the cause and pathogenesis of KS are becoming clearer. As a consequence, new and more effective treatments are being developed.

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Dermatoses of Pregnancy

MANY cutaneous changes occur, during pregnancy, including pigmentary (linea nigra, melasma, darkening of nevi), glandular (increased eccrine and sebaceous gland function, decreased apocrine function), and vascular (spider hemangiomas, palmer erythema, pyogenic granulomas). About 1.6% of women will develop pruritus during pregnancy. Five dermatoses are specific to pregnancy: pruritic urticarial papules and plaques of pregnancy (PUPPP), herpes gestationis (HG), cholestasis of pregnancy (pruritus gravidarum), impetigo herpetiformis, and linear IgM dermatosis of pregnancy (LMDP). Some authors prefer the term "polymorphic eruption of pregnancy" (PEP) to encompass PUPPP, prurigo of pregnancy and pruritic folliculitis of pregnancy.

PUPPP occurs in approximately 1/240 pregnancies, mainly in primigravidas in their third trimester, and is characterized by intensely pruritic urticarial papules and plaques. The lesions typically begin in the striae on the lower abdomen, sparing the periumbilical area, and later spread to involve the breasts, back, and extremities. Pinpoint vesicles may be present, but bullae should raise the clinical suspicion for HG. The latter is confirmed by direct immunofluorescence testing (which is negative in PUPPP). There is no associated fetal morbidity or mortality, but the pruritus is often intractable. The eruption resolves spontaneously shortly after delivery. Although the etiology is unknown, it has been postulated to be related to abdominal distention, and cases involving twin and triplet pregnancies are common. Treatment includes topical steroids and oral antihistamines, but oral corticosteroids may be required in severe cases.

Prurigo of pregnancy may be a distinct entity, or it may represent an unusual variant of PUPPP. It occurs in approximately 1/300 women, with an onset in the 25th to 30th week of pregnancy. Itchy, grouped, excoriated papules develop primarily on the extensor surfaces of the extremities in patients with an atopic diathesis. Treatment is symptomatic, and there is no associated fetal morbidity or mortality.

Pruritic folliculitis of pregnancy is most likely a form of acne/folliculitis that occurs in pregnancy due to hormonal alterations. Patients in their fourth to ninth month of pregnancy develop generalized, excoriated follicular papules and sterile pustules that resolve shortly after delivery. Mid-potency topical corticosteroids and oral antihistamines have been used but without significant benefit in most patients.

HG occurs in 1/7,000 pregnancies. Patients develop severely pruritic, urticarial plaques and tense bullae on the trunk and extremities. The umbilicus is commonly involved. The disease usually requires systemic corticosteroids and may persist for months or years after delivery. A postpartum flare occurs in 75% of patients, and approximately 25% flare with oral contraceptives or menses. About 5% of patients' newborns will have transient blisters; there is an increased risk of prematurity and a tendency for small-for-gestational-age babies. The disease commonly recurs in subsequent pregnancies. In contrast to PUPPP, direct immunofluorescence is positive, revealing linear C3 along the basement membrane zone in 100% of patients.

The incidence of cholestasis of pregnancy varies widely in different countries and ethnic groups. The incidence in North America, for example, is approximately 1/1293, while in Chile and Scandinavia it occurs in 3% to 14% of the population. In this disorder, patients develop severe generalized pruritus, in the absence of primary lesions. The degree of pruritus directly correlates with the level of serum bile acids, which is often markedly elevated. Symptoms begin in the late second to early third trimester and usually resolve within 48 hours of delivery. There is often mild elevation of liver function tests, but if the bilirubin is normal, the disease is referred to as "pruritus gravidarum." Treatment has included phenobarbital, cholestyramine, and ion exchange resin, often without significant benefit. The disease may recur in subsequent pregnancies.

Impetigo herpetiformis has been infrequently reported in the literature. Patients in their third trimester develop generalized pustules on a background of erythema and scaling. The eruption may be accompanied by fever, nausea and vomiting, and leukocytosis. If the patient develops hypocalcemia, she may develop tetany, seizures, and delirium. Because of placental insufficiency, there is an increased risk of stillbirth. The disease remits promptly after delivery. Because of its clinical resemblance to pustular psoriasis and the extremely low levels of skin-derived antileucoproteinase found in patients, this disease is felt to represent a variant of pustular psoriasis.

LMDP is also rarely reported. It occurs in the third trimester as pruritic, red, follicular papules on the trunk and extremities. The eruption resolves within weeks after delivery. A biopsy for direct immunofluorescence reveals linear IgM at the basement membrane zone. Some patients with a similar presentation may have circulating IgM antibodies detected on indirect immunofluorescence testing.

In summary, a number of eruptions occur during pregnancy that have characteristic clinical, histopathological, and laboratory findings. It is important for the clinician to be familiar with these, not only for treatment if it is necessary, but also in order to discuss with the patient the risk of recurrence in subsequent pregnancy and any risk to the fetus or newborn.

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Evaluation and Treatment of Onychomycosis

DISTAL subungual onychomycosis, the most common type of nail fungus, may affect as much as 10% to 12% of the population. In the geriatric age group, this figure may reach as high as 50%. Since older persons are one of the fastest growing segments of our society, tinea unguium becomes a major health problem that causes disability and has a major serious impact on quality of life. Fortunately, in the last several years, three safe and effective oral antifungals have become available for use. The likelihood for a cure is good, but there is approximately a 15% recurrence rate.

Before starting therapy, it is essential that the diagnosis of onychomycosis be confirmed. Since fungal nail infections comprise only 50% of dystrophic nails, it follows logically that other conditions make up the 50% balance. Psoriasis, lichen planus, nail cosmetic sensitivity, and many other disorders also enter into the differential diagnosis. The most commonly used diagnostic tests are the traditional KOH wet mount and culture. If either one or both of these investigations is positive, the diagnosis is proved and therapy may be commenced. Since as much as 30% of these mycologic tests may be negative even in the presence of onychomycosis, two additional steps may become necessary. Histopathology of nail clippings with

PAS staining is an effective and noninvasive method to identify fungi and is accurate well over 90% of the time with the possible exception of very early cases. In the latter situation, the nail plate has not yet been invaded by the fungi and, therefore, hyphae may not be present but that is uncommon. Finally, if all else fails to provide a diagnosis, a nail bed biopsy could be performed which, if eliminating fungus as a causative factor, may then provide a specific diagnosis.

The three new oral antifungal agents that are currently available for the treatment of distal subungual onychomycosis are itraconazole (Sporanox), terbinafine (Lamisil), and fluconazole (Diflucan). These drugs are major breakthroughs for two reasons. First, all three reach the nail plate rapidly, within seven to 21 days. The old standby, griseofulvin, requires six months to reach the distal plate of a finger and 12 months or more to reach the same site in a toe because matrix incorporation is required. The new drugs reach the nail quickly because they diffuse upward from the nail bed and do not require matrix incorporation. Second, whereas griseofulvin disappears from the nail as early as two weeks after treatment is stopped, the new ones remain active in the nail for several months after therapy is discontinued.

Itraconazole was the first product to be approved by the FDA. It is a triazole that is lipophilic, has high protein binding, and strong tissue affinity. Itraconazole may be given on a daily basis at two capsules (100 mg each) per day after meals for two months for fingernails and three months for toenails. The new "pulse" regimen may also be employed and has become a popular form of treatment. It requires two capsules twice daily for one week on and three weeks off. Two pulses are needed for fingernails and three for toenails. Drug interactions leading to adverse sequelae such as heart problems can occur with itraconazole, and the following are contraindicated: cisapride, simvastatin, lovastatin, astemazole, triazolam, and midazolam.

The second product to be approved by the FDA was terbinafine. It is an allyl amine that is also lipophilic. It is given in a dosage of one 250-mg tablet daily for six weeks for fingernails and three months for toenails. There are no contraindicated drug interactions because terbinafine does not interact with the cytochrome P450 system to the extent that azoles do.

The last of the triumvirate, fluconazole, has not yet been approved by the FDA for the treatment of onychomycosis, although it is available for some systemic fungal infections. It, like itraconazole, is a triazole but it is hydrophilic and not lipophilic. The dosage schedule is 150 mg to 300 mg once per week, that is, on an intermittent basis. The treatment duration varies but most cases require five to seven months to clear toenails, at a cost of $400 to $500. Fingernails require less time, and as a result treatment cost is also less. Fluconazole is available in 50 mg, 100 mg, and 200 mg tablets. It is impacted by the cytochrome P450 system and therefore has many drug interactions with which the treating physician must become familiar before prescribing. To date, none has been labeled as contraindicated.

Medical surveillance for patients undergoing treatment should include baseline complete blood count and liver function tests, which should be repeated approximately every six weeks.

In summary, we are now in a new era in the treatment of onychomycosis. It behooves the medical community to revisit this important, though fortunately not life threatening, disease that is much more than a cosmetic problem.

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Public Awareness of the Threat of Melanoma and Performance of Skin Self-examination

THE detection and treatment of melanoma early in its course is critical because survival in persons with early or thin melanoma (equal to or less than 0.75 mm) approaches 100% and falls to 55% for more advanced or thick tumors, greater than 3.00 mm. Skin self-examination for melanoma could enhance its early detection and could reduce mortality from melanoma by 63%. Currently, most melanomas are discovered by patients and their family members. Thus, regular skin self-examination or skin examination with the aid of a partner to see difficult areas, eg, back of legs, back of head, can increase the number of patients who seek medical care early.

In the United States, melanoma incidence and mortality continue to rise each decade. The incidence of melanoma is estimated to be approximately 10 per 100,000, and this may be doubling worldwide every 10 to 15 years. The lifetime risk is estimated to be one in 600 for someone born in 1960 and one in 75 for someone born in the year 2000. While Scotland and Australia have experienced a reduction in melanoma mortality rates following broad public educational campaigns, the United States has not yet experienced such a decline. The recently enhanced public awareness of melanoma and acceptance of skin self-examination brings more worried patients into the offices of all physicians, thus increasing case finding by all health care professionals. The desired decline in U.S. mortality rates could be attained by monthly skin self-examination performed by the at-risk population and proficiency of health care professionals in early detection of melanoma with referral of clinically suspicious cases to the dermatologist for biopsy and treatment. All health care professionals should become proficient in identifying those at high risk of developing a melanoma, informing patients of their individual risk, and counseling patients about how to perform skin self-examination using the ABCD rule (Asymmetry of the shape of the mole, Border irregularity, Color variation over the surface of the mole, and Diameter greater than 6 mm).

Those whose advice may likely be sought, primary care physicians, need sufficient training themselves in identifying clinically suspicious lesions.

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HIV Related Skin Diseases Clear with Combination Therapy

FROM the beginning of the AIDS epidemic in 1981, the skin was observed to be a key barometer of immunodeficiency. Diseases such as seborrheic dermatitis and onychomycosis appear with modest drops in the CD4 count. Kaposi's sarcoma, oral candidiasis, and herpes zoster appear with progressive loss of CD4 cells and, finally, oral hairy leukoplakia, molluscum contagiosum, eosinophilic folliculitis and resistant herpes simplex are seen with profound levels of immunodeficiency.

The association of herpes zoster, oral candidiasis, oral hairy leukoplakia, and molluscum contagiosum is so profound that these cutaneous conditions were used as signs of disease progression in early clinical trials of antiviral medications. Although they are not as precise as the CD4 count in measuring the level of immunodeficiency and are certainly not as useful as the viral load in measuring the rate of disease progression, they are of great value in underdeveloped countries where expensive laboratory tests are not available.

Furthermore, these conditions are so strongly tied to HIV infection that there have now been a number of lawsuits filed against physicians who diagnosed herpes zoster in young people and did not discuss with them the wisdom of having an HIV test performed.

The introduction of combined antiretroviral therapy showed that if the physician was successful in getting the patient's viral load below the level of detection, the patient's disease did not progress, the CD4 count began to rise, and his or her general well-being improved. At the same time, patients with Kaposi's sarcoma showed almost immediate arrest in the rate of progression of their disease with ongoing improvement if the viral load remained below the level of detection. Eosinophilic folliculitis may initially flare with aggressive therapy, but also clears as the CD4 count rises above 100. Molluscum contagiosum becomes easily manageable and candida and oral hairy leukoplakia clear.

Thus in this second phase of the AIDS epidemic, the treatment of choice for most HIV associated skin diseases, including Kaposi's sarcoma, is aggressive antiretroviral therapy and maintenance of the viral load below the level of detection. If the viral load cannot be reduced below the level of detection, the patient will become resistant to the drugs being used and the disease will recur and progress.

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The Role of *Clostridium Botulinum:* A Neurotoxin in Clinical Dermatology

CLOSTRIDIUM botulinum produces seven (A–G) serologically distinct neurotoxins, and type A (Botox, Allergan, Inc., Irvine, Cal.) is the most potent. Upon exposure to striated muscle, it prevents release of acetylcholine from the presynaptic neuron at the neuromuscular junction. The effect of this inhibition is a chemical denervation resulting in flaccid muscle paralysis. This paralytic effect has historically been intimately associated with lethal systemic botulism toxicity. In 1973 small amounts of purified intramuscular Botox were found to be therapeutic for numerous neuromuscular disorders, involving the periocular anatomy. Serendipitously it was realized that with paresis of the underlying hyperkinetic muscles, many wrinkles were effaced without altering cutaneous sensation. Since this initial finding, there has been an exponential surge in the understanding and use of botulinum A exotoxin.

As a sole or as an ancillary procedure, Botox has extraordinary utility in the treatment of the stigmata of facial aging. Injection of 30 to 40 units of Botox into the corrugator supercilii and procerus muscles paralyzes the glabellar complex and improves the deep midline furrow. Smaller amounts, 20 to 30 units, are required to treat the lateral fibers of the orbicularis oculi muscle that causes the crow's feet deformity. The frontalis muscle is the large forehead muscle and contraction causes pronounced horizontal creases. Injection of 50 to 60 units of Botox will effectively eradicate these lines. With age and hyperkinetic movement of the platysma muscle, the neck can prematurely appear senescent with horizontal rhytides and thick vertical platysma bands. Serial injections into the belly of this muscle releases the downward pull of the muscle and results in a reduction in horizontal neck lines and a sharper cervicomental angle. Additionally, there have been reports of treatment of other facial muscles inclusive of the nasalis, mentalis, and orbicularis oris muscles for facial rejuvenation.

The onset of action of Botox is between three to seven days and can persist for many months. Upon muscle reanimation and reappearance of the aesthetic defect, reinjection can be performed at the patient's discretion. Clinical evidence suggests that with each subsequent treatment, there is further muscle atrophy and the duration of the effect of Botox is prolonged.

Botox can also be used synergistically with other facial rejuvenative procedures. Following facial plasty surgery, wrinkles can further be diminished with Botox. Similarly, reducing muscle contraction with Botox before resurfacing or soft tissue augmentation has been found to sustain the effects of both procedures.

In another area, axillary and palmer hyperhidrosis have long been problematic for patients, and despite many different forms of therapy, long-term improvement remains elusive. By inhibiting contraction of the eccrine gland myoepithelial cell, serial intradermal injections of Botox have resulted in a profound reduction in the amount and severity of hyperhidrosis.

The use of Botox therapeutically as well as for facial rejuvenation by paralyzing selected facial muscles has rapidly been embraced by physicians and patients alike. It is remarkably effective and safe, without permanent deleterious side effects and therefore provides an acceptable risk-to-benefit ratio. However, more documentation and follow-up are necessary to establish standard injecting guidelines and define optimal doses and volumes. To reduce the risk of adverse sequelae such as ptosis (eyelid or eyebrow) or facial asymmetry, it remains incumbent upon physicians to be familiar with both the indications for Botox and the muscular anatomy underlying facial expression. It is also prudent to inform patients about the potency and the fact that this is off-label use of the drug (the U.S. Food and Drug Administration has approved Botox for the treatment of strabismus, benign essential blepharospasm, and facial nerve disorders), as well as to advise them about alternative therapies, duration of benefit, and the potential complications.

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Disorders of Pigmentation: Global Issues of Major Cosmetic Concern

PIGMENTARY disorders affect billions of patients globally and cause significant cosmetic disfigurement. Although these lesions occur in all races, they are most visible in darker-skinned individuals. Even though patients experience tremendous despair regarding pigmentary imperfections, they are often not treated and patients may be told that treatments are ineffective.

Dyschromic conditions are characterized by patches of hyperpigmentation, hypopigmentation, or depigmentation. Histological studies often demonstrate a variety of changes, including defects in melanin production, melanin deposition, melanin transfer and/or quantitative alterations in melanocytes. Common dyschromias include melasma, postinflammatory hyperpigmentation, and vitiligo.

Melasma is a common disorder of hyperpigmentation in which typical brown or grayish brown macules appear on the face, including the cheeks, forehead, upper lip, and chin. Although the condition occurs in all racial-ethnic groups, it tends to be most common in darker-skinned individuals and it is observed most often in women.

Factors implicated in the pathology of melasma include ultraviolet radiation, oral contraceptives, pregnancy, and cosmetics. Three clinical patterns of hyperpigmentation are recognized: malar, centrofacial, and mandibular. Histological patterns of pigmentation include epidermal, dermal, and a mixed variety in which excess pigment is deposited in both the epidermis and dermis. Current therapies for melasma are predicated on the severity of clinical lesions. For patients with mild to moderate disease, monotherapies include topical 2% and 4% hydroquinone, azelaic acid, kojic acid, tretinoin, and alpha hydroxy acids. Of these, hydroquinone remains the gold standard. For patients with moderate to severe involvement, approaches using combinations of the aforementioned bleaching agents in conjunction with superficial chemical peels work best. One cannot overemphasize the importance of daily use of broad-spectrum sunscreens in treating melasma.

Postinflammatory hyperpigmentation is characterized by macules or patches of hyperpigmentation that develop in response to cutaneous, injury. Excess pigment deposition may be confined to the epidermis or occur in both the epidermis and dermis. As with melasma, postinflammatory hyperpigmentation tends to be most severe in darker racial-ethnic groups. Pigmentary lesions occur at the site of cutaneous injury, and so may appear on any area of the body. Postinflammatory hyperpigmentation is caused by a variety of inflammatory disorders including acne and eczematoid, papulosquamous, and vesiculo bullous conditions. If the underlying inciting disease is treated, in contrast to melasma, postinflammatory hyperpigmentation may remain quiescent or improve with time. Most patients require some form of therapeutic intervention, however. Therapies include topical bleaching agents (see melasma). Combination therapies using topical bleaches in conjunction with superficial chemical peels may be beneficial in patients with severe disease affecting facial areas. Therapeutic response often correlates with the depth of pigment deposition, ie, deposition in the dermis alone *vs* deposition in both the epidermis and dermis. Maximal results are achieved in patients with only epidermal hyperpigmentation. Significant clinical improvement can be induced in many patients with epidermal and dermal pigment deposition, however, via induction of a decrease in epidermal melanin.

Vitiligo is a common disorder of hypopigmentation affecting 1% to 2% of the population. Macules or patches of depigmentation occur in a localized, acral, acralfacial, generalized or segmental distribution. The disease has an equal incidence in all racial groups. It is most evident in darker racial-ethnic groups, however, because of the striking contrast between depigmented and normal skin. Because of the profound cosmetic disfigurement, patients often experience severe emotional trauma. Histologically the disease is characterized by an absence of cutaneous melanocytes. Proposed theories of destruction of melanocytes include autoimmune, neural, autocytotoxic, biochemical, and viral mechanisms. Autoimmune diseases are increased in vitiligo patients. Thirty percent of patients show evidence of thyroid dysfunction. Despite advances in treatment of vitiligo, dermatologists and nondermatologists regularly inform patients that all treatments are ineffective. These statements are mythical, fallacious, and frustrating. Treatment planning is based on the extent of cutaneous surface involvement and progression of the disease. Therapies include topical steroids, systemic steroids (for extensive, progressive disease), topical and oral photochemotherapy and immunomodulators. In addition, isolated stable lesions can be treated by a variety of surgical grafting procedures. Therapeutic responses are enhanced in children with vitiligo. Many patients achieve moderate to excellent repigmentation. If repigmentation efforts fail in patients with extensive depigmentation affecting more than 50% of the cutaneous surface, therapy using monobenzone may be a viable alternate.

Despite many of the prevailing myths regarding dyschromias, there are safe and efficacious therapies available for treatment of a variety of common disorders of pigmentation.

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Patient-applied Treatment for External Genital Warts: The Time Has Come

GUIDELINES published by the Centers for Disease Control and Prevention and the consensus of a recent American Medical Association panel have categorized two treatment approaches for external genital warts: patient-applied and provider-administered.

Provider-administered therapies include trichloroacetic acid, bichloracetic acid, podophyllin resin, cryotherapy, intralesional interferon, surgical removal, and laser surgery. Patient-applied therapies include podofilox solution or gel and imiquimod cream.

Podofilox is an antimitotic drug which may also damage endothelial cells. Patients apply podofilox twice daily for three days followed by four days off treatment. Four such treatment cycles constitute a course of treatment. Imiquimod is an interferon and Th-1 cytokine inducer. Patients apply the cream three times weekly (on alternate days) for up to 16 weeks.

While all of these modalities are eventually effective in rendering patients wart-free, complex factors influence treatment selection by both patient and provider. There is clearly no ideal treatment for all patients or for all warts.

Genital warts are caused by the low-risk genital human papillomaviruses (HPV) types, predominantly HPV 6. While at least 50% of the sexually active population in the

U.S. are infected with one or more HPVs, only 1% have external genital warts. These HPV types have little, if any, malignant potential. As we have learned to distinguish these types from the high-risk types associated with cervical cancer, there has been a general tendency toward less aggressive therapy.

The goal of treatment of genital warts is the removal of symptoms, which can be emotional as well as physical. Physical symptoms include pain, burning, and bleeding and are relatively rare. The emotional impact of having active viral STD is significant, however.

While there is no convincing evidence that patient-applied therapies are superior to provider-administered therapies, an important consideration is patient preference. In the long-term, the major effect of genital warts on many patients is not the bumps or growths, but rather the emotional consequences of this infection on them, their relationships, and their sexuality. The availability of patient-applied therapies allows the patient to have some control over this difficult problem.

The major question is whether the patient wishes the physician to treat the warts or wishes to treat the warts him/herself. In addition, there is a need for education about the natural history of HPV infection. Although HPV infection and external genital warts are common, many patients before diagnosis have heard of neither.

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Lasers for Removing Unwanted Hair and Rejuvenating Skin

THE use of lasers for treating a variety of skin diseases demonstrates the precision and selectivity provided by these devices that reduce the risk of complications and enhance the opportunity for a satisfactory outcome. Several of the newest uses for lasers are removing unwanted hair and rejuvenating sun-damaged or aged skin.

Removal of hair with little discomfort and excellent long-term results by light from lasers or nonlaser sources can be accomplished with two different techniques. The first technique employs the topical introduction of a carbon-based material in mineral oil into the hair follicle that absorbs infrared light from a Q-switched Nd:YAG laser. The mechanism of action for this technique is a combination of thermal and mechanical injury to the germinative cells of the follicle that are in contact with the carbon particles. A second technique uses the absorption of light by melarun—found between matrix cells in the hair bulb and in the structural elements of the hair shaft medulla, cortex and cuticle—to injure the hair follicle. The mechanism of action for this group of lasers is largely thermal. In order to have an effect on hair growth, precise damage must be done to follicle germinal cells. Since the absorption spectrum for melarun is broad, many wavelengths of light from several different devices can be used to remove hair. The Food and Drug Administration (FDA) has given clearance for treating unwanted hairs to the long-pulse ruby, the alexandrite and diode lasers as well as an intense light source. Some of these devices use contact or spray cooling to reduce thermal injury to the pigmented epidermis as the treatment is being performed. The use of nonlaser light from a flashlamp that produces an intense source of white light that is filtered to deliver wavelengths greater than 590 nm for effectively removing unwanted hair has recently been reported. This system allows adjustments in both the pulse duration and wavelength, depending on the clinical situation and the color the patient's skin and hair to provide additional flexibility.

All current treatment techniques for removing hair are performed in ambulatory settings either without anesthesia or with topical anesthesia alone. The treatment may produce minimal postoperative edema or transient erythema lasting 24 to 48 hours. Although hair follicles have tremendous regenerative capabilities that vary greatly from individual to individual and from one anatomic site to another, typically a delay in hair regrowth will average three to six months after a single treatment. Treating the same area sequentially as hairs begin to regrow improves the response by reducing the caliber and lightening the color of the remaining hairs and increasing the number that are permanently removed. Recently, the long-pulse ruby laser has received FDA clearance to use the term "permanent reduction" in hair following treatment, based on analysis of long-term followup data. Unlike the technique employed with electrolysis, which treats only one hair at a time, all of these new devices allow for the simultaneous treatment of many hairs with a single pulse of light, so that relatively large areas of involvement, such as the legs, chest or back, can be treated quickly. The cost of performing this treatment is generally dependent on the size of the treatment area and the time required to perform the treatment.

Treatment options for rejuvenation of sun-damaged or aged skin have been radically changed by the recent introduction of short-pulsed, high-energy carbon dioxide lasers. These devices precisely remove the solar damaged epidermis and dermis, tighten collagen, and greatly improve the appearance of most patients. However, reports of prolonged erythema, occasional scarring, and permanent hypopigmentation reduced the acceptance of this technique and led to the introduction of the erbium:YAG laser for skin rejuvenation. The high coefficient of absorption by water for the erbium:YAG laser greatly minimizes the amount of unwanted collateral thermal injury, speeds healing time and reduces postoperative erythema. The erbium:YAG laser technique is generally most useful for younger patients or those individuals with early signs of photodamage. This is due to the fact that many more repetitions or passes are required during the single treatment session to achieve the same depth of ablation as with the carbon dioxide laser. However, reduction in side effects with this laser system make it a welcome addition to the techniques used in treating sun-damaged or aged skin. The cost of performing laser skin resurfacing is generally similar or slightly higher than the cost associated with the older dermabrasion technique but with the added benefits of greater precision, rapid healing and a more predictable outcome.

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Antimicrobial Switch Therapy

KHANH BUI, PHARM.D. AND RICHARD QUINTILIANI, M.D.

AS the total yearly expenditures for health care continues to rise, economic pressure has forced hospitals to become more cost conscious. In fact, the survival and success of a hospital in the managed-care era depends on its ability to respond to these fiscal restraints. This burden is ultimately passed down to individual departments, which are faced with making decisions that are both clinically and fiscally sound. Since a considerable percentage of the pharmacy budget is spent on intravenous (IV) antimicrobials, reducing their usage by switching to oral therapy will often result in substantial economic savings for this and other departments.

Changing from IV to oral therapy is nothing new. Several terms such as antimicrobial streamlining, switch therapy, transitional therapy, step-down therapy, or sequential therapy have been adopted to describe this practice.[1-4] The goal is to reduce the use of IV therapy in those infections in which oral therapy will provide the same anti-infective results. Moreover, the patient, the infectious organism, and the antimicrobial agent form a triad that must be taken into account when switch therapy is initiated.

Considerations for Switch Therapy

Investigators who have studied switch therapy usually require that patients have been improving clinically for at least 24 hours, based mainly on an assessment of the laboratory and physical findings along with defervescence.[2] Other factors that influence this decision include the patient's ability to ingest tablets, capsules, or liquids orally or through a nasogastric or nasoduodenal tube. At Hartford Hospital it is also recommended that candidates for this program meet additional criteria such as heart rate ≤100 beats per minute, spontaneous respiratory rate ≤24 breaths per minute, and a systolic blood pressure of ≤90 mm Hg without the aid of vasopressor agents.[5] These are not strict guidelines, but they serve as starting points for identifying patients who may be candidates for conversion to oral antibiotics.

Although the infectious organism is important in the clinical outcome, it is the least likely component of this triad to determine the route of antimicrobial administration. Unless an organism is resistant to all oral products, this should not be a barrier to switch therapy. To kill bacteria, the antibiotic must attain a high enough concentration at the site of infection for a long enough period of time. This principle is underscored in antimicrobial pharmacodynamic parameters that rely only on drug exposure over time in comparison to the bacterial susceptibility. The rate and extent of killing is irrespective of the route used for administration so long as an adequate exposure is provided. Although pathogens are intricate, they have no way to recognize how a drug is introduced into their environment! Effective concentrations of drugs are those high enough to inhibit growth.

The final element to consider for switch therapy is the properties of the drugs. Although some drugs are available only in parenteral formulation, this does not keep the clinician from choosing an oral product with the same spectrum of activity. This is often the rationale when conversion therapy has been performed with cephalosporins,[2,3] like the replacement of IV third-generation agents (eg, cefotaxime, ceftizoxime, or ceftriaxone) with oral

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Table 1.—Recommended Treatments for Community- and Hospital-acquired Pneumonia[5]
(Note: Antibiotics are not listed in order of preference)

Suspected pathogens	Intravenous drug(s)	Intravenous dose(s)	Oral drug(s)	Oral dose(s)
Community-acquired Pneumonia				
	Azithromycin	500mg q24hr	Azithromycin/	500mg q24hr
S. pneumoniae	—	—	Clarithromycin	500mg q12hr
			—	—
H. influenzae	Cefotaxime	1g q12hr	Cefpoxdime/	200mg q12hr
	plus		Cefixime	400mg q24hr
M. catarrhalis	Erythromycin	500mg q6hr	plus	
			Erythromycin	500mg q6hr
Atypicals	—	—	—	—
(Chlamydia,	Trovafloxacin	200mg q24hr	Trovafloxacin	200mg q24hr
Mycoplasma,	—	—	—	—
Legionella)	Levofloxacin	500mg q24hr	Levofloxacin	500mg q24hr
Hospital-acquired Pneumonia				
			Cefixime	400mg q24hr
S. pneumoniae	Cefotaxime	1g q12hr	or	
H. influenzae	—	—	Cefotaxime	200mg q12hr
M. catarrhalis	Trovafloxacin	300mg q24hr	—	—
Enterobacteriaceae	—	—	Trovafloxacin	200mg q24hr
Oral anaerobes			—	—
	Levofloxacin	500mg q24hr	Levofloxacin	500mg q24hr
Above plus				
Ps. aeruginosa	Cefepime	1-2g q12hr	Trovafloxacin	200mg q24hr
(immunocompetent patient)	—	—	—	—
	Meropenem	1g q8hr	Levofloxacin	500mg q24hr
Above plus	Piperacillin/tazobactam	4.5g q8hr		
Ps. aeruginosa	plus			
(immunocompromised patient)	Aminoglycoside	Nomogram	Trovafloxacin	200mg q24hr
	Cefepime	1-2g q12hr		
	plus		Levofloxacin	500mg q24hr
	Trovafloxacin	300mg q24hr		
	or			
	Levofloxacin	500mg q24hr		

third-generation drugs (eg, cefpodoxime, cefixime). Other considerations when deciding on an antibiotic for switch therapy include its pharmacokinetics, bioavailability (proportion of dose absorbed), convenience, potential drug-drug interactions, and tolerability. Antimicrobials that have high bioavailability (consistently exceeding 80%) are most fluoroquinolones, fluconazole, trimethoprim/sulfamethoxazole, metronidazole, clindamycin, minocycline, and first generation cephalosporins (eg, cephalexin, cephradine, cefadroxil).[6-9]

Patient and Institutional Benefits

Switch therapy provides benefit to the patients as well. Without the need for cumbersome IV catheters, lines, and IV poles, patients are more mobile. They are able to move freely and ambulate, use the restroom, or simply get to a chair without much assistance from staff members. Patients are also more comfortable when they do not have to undergo IV catheter insertion and maintenance. While these matters may appear trivial, they indicate to the patient that an improvement has been noted.

Table 2. Recommended Treatments for Community and Hospital Acquired Intra-abdominal Infections[5]
(Note: Antibiotics are not listed in order of preference)

Suspected pathogens	Intravenous drug(s)	Intravenous dose(s)	Oral drug(s)	Oral dose(s)
Community-acquired Intra-abdominal Infections				
Enterobacteriaceae	Ampicillin/sulbactam	1.5g q6hr		
(common)	—	—		
	Cefotaxime/	1g q12hr	Amoxicillin/clavulanate	875mg q12hr
Bacteroides spp.	Ceftizoxime/	1g q12hr	—	—
	Cetriaxone	1g q24hr		
Staph/Strep	plus		Trovafloxacin	
(treatment or prophylaxis)	Metronidazole	500mg q12hr	200mg q24hr	
	—	—		
	Trovafloxacin	300mg q24hr		
	—	—		
	Cefotetan	1-2g q12hr		
Above plus Chlamydia	Ampicillin/sulbactam	1.5g q6hr	Amoxicillin/clavulanate	875mg q12hr
(eg. PID)	plus		plus	
	Doxycycline	100mg q12hr	Doxycycline	100mg q12hr
	—	—	—	—
	Trovafloxacin	300mg q24hr	Trovafloxacin	200mg q24hr
Hospital-acquired Intra-abdominal Infections				
Enterobacteriaceae	Cefepime	1-2g q12hr		
(common and	plus			
unusual)	Metronidazole	500mg q12hr		
Bacteroides spp.	—	—		
Staph/Strep	Trovafloxacin	300mg q12hr	Trovafloxacin	200mg q24hr
Above plus	Piperacillin/tazobactam	4.5g q8hr		
Enterococcus or	plus			
Ps. aeruginosa	Aminoglycoside	Nomogram		

From an institutional perspective, the cost savings with this type of program benefit many departments. A reduction in IV antibiotic usage will reduce pharmacy expenditures. At Hartford Hospital the estimated daily cost of an IV antibiotic is eight times greater than an oral alternative. This cost comprises of pharmacist, pharmacy technician, and nursing preparation and delivery time. Although many safeguards have been built into the system of medication delivery, the chance for error is higher when administering IV medications because of the many steps involved. Medications account for only a small percent of the total hospitalization cost in comparison to the length-of-stay cost or adverse events. Unfortunately, not identifying and transitioning stable patients quickly enough will only cause them to accumulate unnecessary hospital days. Early discharge of a patient prevents prolonged exposure to nosocomial pathogens. Infection due to a nosocomial organism often increases morbidity and mortality. Over a three-year period at Hartford Hospital, it was reported that 105 (16%) of the total bacteremia cases were directly attributable to organisms isolated from the catheter tip and blood.[1] Using the range of cost for treating an episode of catheter-related sepsis at $4,000 to $6,000,[10] investigators at Hartford Hospital estimated the total cost of treating these bacteremia cases to be $420,000 to $630,000.[11]

To promote the conversion of IV to oral antibiotic use, Hartford Hospital developed a pocket-sized expandable card to assist clinicians' decision making. The seventh edition of the card has recently become available for 1998.[5] When applicable, the card groups the sites of infections with the most likely pathogen and then it offers a number of antibiotic choices that are in the hospital formulary. A portion of this card is shown in Tables 1, 2, and 3. The intravenous choices are listed with an oral option to be used when patient improvement is noted.

Table 3. Recommended Treatments for Skin/Soft Tissue/Bone and Urinary Tract Infections[5]
(Note: Antibiotics are not listed in order of preference)

Suspected pathogens	Intravenous drug(s)	Intravenous dose(s)	Oral drug(s)	Oral dose(s)
Skin/Soft Tissue/Bone Infections				
	Cefazolin	1g q8hr	Cephalexin	500mg q6hr
S. aureus (MS)	or		or	
Group A Strep	Clindamycin	300mg q8hr	Clindamycin	300mg q8hr
Above plus	Ampicillin/sulbactam	1.5-3g q6hr	Amoxicillin/clavulanate	875mg q12hr
anaerobes,	or		or	
enterobacteriaceae	Trovafloxacin	200mg q24hr	Trovafloxacin	200mg q24hr
	Piperacillin/tazobactam	4.5g q8hr		
	plus			
Above plus	Aminoglycoside	Nomogram		
Ps. aeurginosa	—	—	Trovafloxacin	200mg q24hr
	Cefepime	1-2g q12hr		
	plus			
	Trovafloxacin	300MG Q24HR		
	Meropenem/Imipenem	1G Q8HR		
Urinary Tract Infections				
Enterobacteriaceae	Ampicillin	1g q6hr		
Ps. aeruginosa		plus	Based on antimicrobial	
Enterococcus	Aminoglycoside	Nomogram	susceptibility	

Conclusion

An aggressive approach to antimicrobial switch therapy benefits both the patient and hospital. A reduction in the length of stay lowers costs. Switching from an IV to oral drug as soon as possible helps to achieve this goal. Although early outcomes studies have been promising, additional data will be needed to assess the economic and health effects. This program is neither difficult to implement nor execute.

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Update: Syringe Exchange Programs—United States, 1997

As of December 1997, more than one third (36%) of the 641,086 cases of acquired immunodeficiency syndrome (AIDS) reported to CDC were directly or indirectly associated with injecting-drug use.[1] Syringe exchange programs (SEPs) are one of the strategies employed to prevent infection with human immunodeficiency virus (HIV) among injecting-drug users (IDUs). The goal of SEPs is to reduce the transmission of HIV and other bloodborne infections associated with reuse of blood-contaminated syringes for drug injection by providing sterile syringes in exchange for used, potentially contaminated syringes. This report summarizes a survey of U.S. SEP activities during January-December 1997 and compares the findings with those of two previous surveys during 1994-1995 and 1996 (2,3). The findings indicate continued expansion in the number, geographic coverage, and activity of SEPs in the United states.

In November 1997, the Beth Israel Medical Center (BIMC) in New York City, in collaboration with the North American Syringe Exchange Network (NASEN), mailed questionnaires to the directors of 113 SEPs in the United States that were members of NASEN. From December 1997 through March 1998, BIMC contacted SEP directors to conduct structured telephone interviews based on the mailed questionnaires. SEP directors were asked about their program's legal status, number of syringes exchanged during 1997, program operations, services provided, budgets, and community and law enforcement relations.

Of the 113 SEPs, 100 (89%) participated in the survey. Of these, 54 began operating before 1995; 20, in 1995; 18, in 1996; and eight, in 1997. One SEP closed in 1997. These 100 SEPs reported operating in 80 cities in 30 states, the District of Columbia, and Puerto Rico[§]; 52 (52%) of the SEPs were located in four states (California [19], New York [14], Washington[11], and Connecticut [eight]). Nine cities had at least two SEPs[¶] (31 SEPs in the nine cities). In the 1996 survey, 87 SEPs reported operating in 71 cities in 26 states, the District of Columbia, and Puerto Rico and during 1994–1995, a total of 60 SEPs reported operating in 46 cities and in 21 states.[2,3]

In 1997, a total of 96 of the 100 SEPs provided information about the number of syringes and reported exchanging approximately 17.5 million syringes (median: 57,343 syringes per SEP) (Table 1). The 10 largest volume SEPs (ie, those that exchanged $\geq$ 500,000 syringes) exchanged approximately 10.3 million (59%) of all syringes exchanged.[◊] The SEP in San Francisco reported exchanging the largest number of syringes (1.9 million) in 1997. During 1996, a total of 84 SEPs reported exchanging approximately 14 million syringes (median: 36,017) and in 1994, a total of 55 SEPs exchanged eight million syringes (median: 39,014).

Most of the 100 SEPs provided other public health and social services: 99% offered instruction in the use of condoms and dental dams to prevent sexual transmission

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[§] California (19 SEPs); New York (14); Washington (11); Connecticut (eight), Massachusetts (five); New Jersey, Oregon, and Puerto Rico (three each); Arizona, Colorado, Illinois, Michigan, Minnesota, Ohio, Pennsylvania, Texas, and Wisconsin (two each); and one each in Alaska, District of Columbia, Florida, Georgia, Hawaii, Indiana, Kansas, Louisiana, Maryland, Missouri, Montana, New Hampshire, North Carolina, Rhode Island, and Tennessee. Staff of one SEP asked its location not be reported.

[¶] The following cities have multiple SEPs: New York (12); Los Angeles, Portland, and Seattle (three each); and Boston, Cleveland, Minneapolis, New Haven, and Sacramento (two each).

[◊] States with the 10 largest volume SEPs were: California (three SEPs); New York and Washington (two each); and one each in Illinois, Maryland, and Pennsylvania. The largest volume SEPs were San Francisco AIDS Foundation, California (1.9 million syringes exchanged); Chicago Recovery Alliance, Illinois (1.6 million); Clean Needles Now, Los Angeles, California (1.0 million); Point Defiance AIDS Project, Tacoma, Washington (1.0 million); Seattle-King County Department of Public Health Needle Exchange Program (NEP), Seattle, Washington (0.9 million); Alameda County SEP, Oakland, California (0.8 million); Prevention Point, Philadelphia, Pennsylvania (0.8 million); Baltimore City NEP, Maryland (0.8 million); Lower East Side NEP, Manhattan, New York (0.8 million); and New York Harm Reduction Educators, Bronx, New York (0.7 million).

Table 1.—Number and percentage of syringe exchange programs (SEPs) and sterile syringes provided by SEPs, by size of program—United States, 1997

	SEPs		Total syringes exchanged	
Size of SEP*	No.	(%)	No.	(%)
< 10,000	24	(25)	82,356	(0.5)
10,000–55,000	24	(25)	700,274	(4.0)
55,001–499,999	38	(40)	6,334,375	(36.3)
≥ 500,000	10	(10)	10,330,103	(59.2)
Total	96	(100)	17,447,108	(100.0)

*Based on the number of syringes exchanged in 1997.

of HIV and other sexually transmitted diseases (STDs); 96% provided IDUs with information about safer injection techniques and/or use of bleach to disinfect injection equipment; and 94% referred clients for substance abuse treatment programs. Health-care services offered on site included HIV counseling and testing (64%), tuberculosis skin testing (20%), STD screening (20%), and primary health care (19%).

In this survey, SEPs were defined as legal if they operated in a state that had no law requiring a prescription to purchase a hypodermic syringe (ie, a prescription law) or had an exemption to the state prescription law allowing the SEP to operate; illegal-tolerated if they operated in a state with a prescription law but had received a formal vote of support or approval from a local elected body (eg, city council); and illegal-underground if the SEP operated in a state with a prescription law but had not received formal support from local elected officials. In 1997, a total of 52 SEPs were legal, 16 were illegal-tolerated, and 32 were illegal-underground.

SEPs reported receiving financial support from various sources including foundations, individuals, and state and local governments. Current federal law prohibits the use of federal funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

The 100 SEPs operated in various settings, including home visits (37%) (syringe pick-up/drop-off sites), storefront locations (35%), vans (35%), sidewalk tables (23%), on-foot outreach (23%), cars (19%), locations where IDUs gather to inject drugs (ie, shooting galleries) (17%), and health clinics (11%). Sixty-nine (69%) SEPs operated in multiple settings. Ninety-five SEPs reported data on the hours of program operation each week; they reported providing 2078.5 hours (median: 18 hours; range: 1–112 hours) of SEP services each week.

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Editorial Note: The findings in this survey indicate continued growth in the number, geographic coverage, and activity of. SEPs in the United States. From 1994-1995 to 1997, there were increases in the number of SEPs participating in these surveys (67% [from 60 to 100]), the number of cities with SEPs (74% [from 46 to 80]), and the number of syringes exchanged (119% [from 8 million to 17.5 million]). However, the scope of SEP activity may be underestimated because some of the known SEPs in the United States did not participate in this survey and some may not be members of NASEN.

The 10 largest volume SEPs are responsible for approximately half of all syringes exchanged in 1997, and the 24 smallest volume SEPs (ie, those that exchanged <10,000 syringes) reported exchanging only <1% of total syringes (mean: 3,431.5 syringes per program). An IDU makes approximately 1,000 illicit drug injections per year.[4] Larger volume SEPs could have greater community impact in allowing IDUs to use a sterile syringe for every injection.

Many IDUs who participate in SEPs are high-risk drug users, suggesting that SEPs can reach persons at risk for bloodborne infections (including HIV and hepatitis C) and other public health problems.[5,6] IDUs who participate in SEPs increase the proportion of drug injections in which a syringe is used only once, thereby reducing the reuse of potentially contaminated syringes.[7] In addition, IDUs using syringes obtained from SEPs have lower rates of HIV incidence (compared to IDUs using syringes obtained from the illicit market).[8] Compared with clients referred to substance abuse treatment programs from other sources, IDUs referred by SEPs have comparably good short-term treatment outcomes.[9] SEPs are one component of a community's comprehensive approach currently used to prevent HIV infection among IDUs, their sexual partners, and their children. Access to sterile syringes for drug users who continue to inject also can be provided through the sale of syringes in pharmacies. In addition to SEPs, comprehensive programs for reducing the spread of HIV and other bloodborne infections should include community outreach programs, substance abuse treatment programs, HIV-prevention programs in jails and prisons, prevention of initiation of drug injection, health care for HIV-infected IDUs, and HIV risk-reduction counseling and testing for IDUs and their sexual partners.[10]

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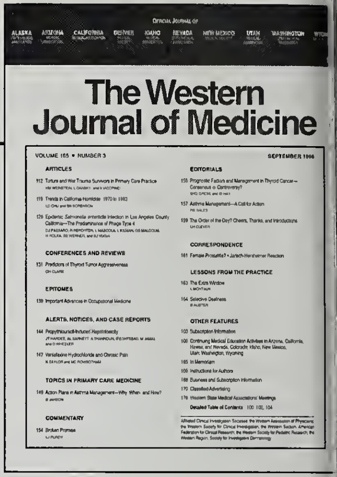

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New “Triptans” and Other Drugs for Migraine

Three new 5-HT$_1$ receptor agonists (“triptans”) have been marketed recently for treatment of migraine. Some drugs for prevention of migraine are listed in Table 2. Treatment of migraine in the emergency room, which may involve use of intravenous drugs, is not included here.

Table 1.—Some Drugs for Treatment of Migraine

Drug	Dosage[1]	Cost[2]
Ergot Alkaloids		
Dihydroergotamine		
D.H.E. 45 (Novartis)	1 mg IM; can be repeated twice at 1-hour intervals (max. 3 mg/attack)	$ 12.65
Migranal Nasal Spray (Novartis)	one spray (0.5 mg)/nostril, repeated 15 minutes later (2 mg/dose; max. 3 mg/24 hours)	16.20
Ergotamine 1 mg/caffeine 100 mg	2 tablets orally, then 1 q30min. x 4 PRN (max. 6 tabs/attack)	
Ercaf (Geneva)		1.04
Gotamine (Vita Elixir)		.30
Wigraine (Organon)		1.26
Ergotamine	2-mg sublingual tablet, can be repeated q30 min. x 2 PRN (max. 3 tabs/attack)	3.95
Ergomar (Lotus Biochemical)		
Ergotamine 2 mg/caffeine 100 mg	One rectal suppository; can be repeated once, 1 hour later	
Cafergot (Novartis)		4.86
5-HT$_1$ Receptor Agonists (“Triptans”)		
Naratriptan—Amerge (Glaxo Wellcome)	1- or 2.5-mg tablet, can be repeated 4 hours later (max. 5 mg/24 hours)	14.92
Rizatriptan—*Maxalt* (Merck)	5- or 10-mg tablet or wafer *(MLT);* can be repeated in 2 hours (max. 30 mg/24 hours)[3]	13.50
Sumatriptan—Imitrex (Glaxo Wellcome)	6 mg SC; can be repeated in 1 hour (max. 2 injections/24 hours)[4]	43.30
	25, 50 or 100 mg orally[5]; can be repeated in 2 hours (max. 200 mg/24 hours)	14.26
	5 or 20 mg intranasally; can be repeated after 2 hours (max. 40 mg/24 hours)	21.94
Zoimitriptan—Zomig (Zeneca)	2.5 or 5 mg orally; can be repeated in 2 hours (max. 10 mg/24 hours)	13.13
Opioid Analgesics		
Butorphanol—*Stadol NS* (Bristol-Myers Squibb)	One spray in one nostril; can be repeated in the other nostril in 60-90 minutes; the same two-dose sequence can be repeated in 3 to 5 hours	4.64–8.71[6]

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1. Recommended by the manufacturer.
2. Cost of treating one migraine attack using lowest recommended dosage, based on wholesale price (HCFA or AWP) listings in *Drug Topics Red Book* 1998 and September *Update.*
3. Patients taking propranolol should only use the 5-mg tablet or wafer (max. 15 mg/24 hours).
4. Preferably in the lateral thigh or deltoid. A second dose is not usually effective if pain does not respond to the first but is recommended for treatment of a recurrent migraine attack.
5. The recommended oral dose of sumatriptan is 25, 60, or 100 mg in the USA; in Europe and Canada it is 50 or 100 mg. Some data suggest that 100 mg may not provide greater relief than 60 mg.
6. Each 2.5-mL bottle contains 25 mg of butorphanol and supplies 8 to 15 1-mg doses depending on frequency of use. With intermittent use, the spray pump must be re-primed.

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ANALGESICS—Treatment with an analgesic may be sufficient for mild or moderate forms of migraine. **Aspirin** can be effective; it is widely used for treatment of migraine both alone and in combinations such as *Fiorinal,* which also contains caffeine and butalbital. **Acetaminophen** has been used for migraine both alone and in combinations such as *Midrin,* which also contains isometheptene and dichloralphenazone. A combination of acetaminophen with aspirin and caffeine *(Excedrin Migraine)* was recently approved by the FDA for use in mild to moderate migraine (Lipton RB, et al: *Arch Neurol* 1998; 55:210). Other nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen sodium *(Anaproxi* and others) have also been effective in relieving the pain of some migraine attacks. Decreased gastric motility during an acute migraine attack may interfere with absorption of analgesics, and overuse (more than two or three times a week) can cause an increase in headache frequency ("analgesic rebound"). Metoclopramide *(Reglan,* and others) taken promptly at the onset of symptoms can enhance absorption of other oral drugs by increasing gastric motility and prevent the nausea associated with many migraine attacks.

Oral opioid combinations and injected opioids are effective for relief of pain, but they produce the usual opioid adverse effects, and frequent use can lead to drug dependence. **Butorphanol** nasal spray *(Stadol NS),* an opioid agonist-antagonist, has been effective for relief of moderate to severe migraine, but psychiatric reactions and drug abuse have occurred (Fisher MA, Glass S: *Neurology* 1997; 48:1156).

ERGOT ALKALOIDS—Ergotamine tartrate, a nonspecific serotonin agonist and a vasoconstrictor, has been used for many years for treatment of moderate to severe migraine headache; it is most effective when taken early in an attack. When used more than two days a week, it can cause rebound headache. Ergotamine is available alone in sublingual tablets and combined with caffeine in oral tablets and suppositories. Nausea and vomiting are fairly common with ergotamine, but can be prevented by pretreatment or concurrent use of an antiemetic, such as prochlorperazine *(Compazine,* and others). Serious adverse effects, such as vascular (including coronary) occlusion and gangrene, are rare, but can occur with overdosage (more than 6 mg in 24 hours or 10 mg per week). These effects may be potentiated by triptans, beta-adrenergic blockers, dopamine *(Intropin,* and others), or CYP3A4 inhibitors such as erythromycin (*The Medical Letter Handbook of Adverse Drug Interactions,* 1998, page 206). Liver disease or fever can accelerate symptoms of ergotism.

Dihydroergotamine, which can be injected subcutaneously, intramuscularly or intravenously, or sprayed intranasally, is also effective in treating migraine attacks unresponsive to analgesics. It is a weaker arterial vasoconstrictor than ergotamine and causes fewer adverse effects; it can cause diarrhea and muscle cramps, but rebound headache apparently does not occur. Dihydroergotamine nasal spray *(Migranal)* relieves migraine after two hours in about 50% of patients, with a 15% incidence of headache recurrence within 24 hours. In one study, subcutaneous sumatriptan was more effective, but had a higher recurrence rate (Touchon J, et al: *Neurology* 1996; 47:361).

5-HT$_1$ RECEPTOR AGONISTS ("TRIPTANS")— Sumatriptan *(Imitrex)* has been marketed in the USA in a formulation for subcutaneous self-injection, in an oral formulation and as a nasal spray. A selective serotonin-receptor agonist with a short duration of action, it appears to be more effective than ergotamine for treatment of acute migraine attacks. In general, the injection and nasal spray formulations begin to produce relief in 10 to 15 minutes, compared to one to two hours with the tablets. A subcutaneous injection of sumatriptan produces relief within two hours in 70% to 80% of patients with moderate to severe migraine. In one study, with sumatriptan nasal spray, about 60% of patients obtained relief after two hours (Ryan R, et al: *Neurology* 1997; 49:1225). Oral sumatriptan has been effective in about 50% to 60% of patients with acute migraine after two hours and in about 70% after four hours (Perry CM, Markham A: *Drugs* 1998; 55:889).

Three new triptan tablet formulations were recently approved by the FDA: **zolmitriptan** *(Zomig—Medical Letter* 1998; 40:27), **naratriptan** *(Amerge),* and **rizatriptan** *(Maxalt).* Rizatriptan is also available as a wafer that dissolves on the tongue *(Maxalt-MLT).* Zolmitriptan and rizatriptan may have a more rapid onset of action than oral sumatriptan, but adequate comparative studies are lacking. Naratriptan, which has a longer half-life, appears to have a slower onset of action. The rate of recurrence of migraine within 24 hours after treatment with a triptan is generally 30% to 40%; it may be slightly lower with naratriptan (Mathew NT, et al: *Neurology* 1997; 49:1485).

A burning sensation at the site of injection is common with sumatriptan. Tingling, flushing, dizziness, drowsiness, fatigue, and a feeling of heaviness, tightness and pressure in the chest may occur with all triptans, but may be more common with the injectable form of sumatriptan. The chest discomfort is usually benign, but angina and myocardial infarction occur rarely (Visser WH, et al: *Neurology* 1996; 47:46; Main ML, et al: *Ann Intern Med* 1998; 128:874).

Drug Interactions—A triptan should not be used within 24 hours after another triptan or any ergo/amine-containing drug because vasoconstriction could be additive, and patients should be warned not to take ergot derivatives until 24 hours or more after a triptan. A "serotonin syndrome” of weakness, hyperreflexia and incoordination has been reported in patients taking a selective serotonin-reuptake inhibitor (SSRI) with a triptan (Jaffe RT, Sokolov STH: *Acta Psychiatr Scand* 1997; 95:551). All triptans except naratriptan are contraindicated in patients taking an MAO inhibitor or within two weeks of stopping one. Propranolol (Inderal, and others) increases serum concentrations of rizatriptan and possibly zolmitriptan.

PROPHYLAXIS—Patients with frequent or severe migraine headaches or those refractory to symptomatic treatment may benefit from prophylaxis. Menstrual or other predictable migraine attacks may sometimes be prevented by a brief course of ergotamine or an NSAID, such as naproxen sodium *(Anaprox,* and others), taken for several days before and during the first few days of menstruation.

Table 2.—Some Drugs for Prevention of Migraine

Drug	Dosage[1]	Cost[2]
Propranolol—generic price	80 to 240 mg/day, divided bid, tid or qid	$ 1.22
Inderal (Wyeth-Ayerst)		42.40
Timolol—generic price	10 to 15 mg bid	15.41
Blocadren (Merck)		34.19
Divalproex sodium—Depakote (Abbott)		250 mg bid or tid46.05
Verapamil—generic price	80 mg tid or qid	4.32
Calan (Searle)		48.76
Methysergide—*Sansert* (Novartis)	4 to 8 mg/day, divided bid or tid	121.38

1. Recommended by the manufacturer.
2. Cost to the pharmacist for 30 days’ treatment with lowest daily dosage based on wholesale price (HCFA or AWP) listings in *Drug Topics Red Book 1998* and September *Update.*

Metoprolol *(Lopressor,* and others), nadolol *(Corgard,* and others) and atenolol *(Tenormin,* and others) have also been effective in preventing migraine, according to *Medical Letter* consultants. All beta-blockers can cause fatigue, exercise intolerance, depression, and orthostatic hypotension, and in the short term may aggravate heart failure. All are contraindicated in patients with asthma.

Valproate *(Depakote),* an anticonvulsant, has been effective in decreasing migraine frequency and has been approved by the FDA for prevention of migraine (Silberstein SD: *Headache* 1996; 36:547). Its effectiveness was equal to that of propranolol in one study (Kaniecki RG: *Arch Neurol* 1997; 54:1141). Common adverse effects include nausea, weight gain, and fatigue. Valproate taken during pregnancy can cause congenital abnormalities such as neural tube defects.

Tricyclic antidepressants can prevent migraine in some patients and may be given concurrently with other prophylactic agents, but often cause weight gain. Amitriptyline *(Elavil,* and others) in dosage ranging from 10 to 150 mg per day has probably been used more for this purpose than other antidepressants (Ziegler DK, et al: *Arch Neurol* 1993; 50:825).

Calcium-channel blockers have also been tried for prevention of migraine. Verapamil *(Calan,* and others) has been moderately effective in a few placebo-controlled trials (Solomon GD: *Headache* 1989; 29:425), but is not FDA-approved for prevention of migraine.

Methysergide *(Sansert),* another ergot alkaloid, is effective for prevention of migraine, but may cause weight gain, peripheral edema and, with more than six months’ use, retroperitoneal, pleuropericardial and subendocardial fibrosis. Major vessel constriction, mesenteric vascular fibrosis, and small bowel infarction have been reported rarely. Concurrent use with other ergot alkaloids, a triptan, beta-adrenergic blockers, dopamine or a CYP3A4 inhibitor such as erythromycin may increase the risk of arterial spasm and occlusion *(The Medical Letter Handbook of Adverse Drug Interactions,* 1998, page 206). Methysergide should be reserved for severe refractory migraine. Many clinicians recommend a four-week interval without the drug every six months, but whether this practice decreases toxicity is unclear.

Nonsteroidal anti-inflammatory drugs (NSAIDs), particularly naproxen sodium and flurbiprofen, have been used for prevention of migraine as well as for aborting acute attacks. Ergot alkaloids in small doses, as in *Bellergal-S* (ergotamine tartrate 0.6 mg, phenobarbital 40 mg, and bellafoline 0.2 mg), have been used for decades for migraine prophylaxis, particularly for menstrual-related migraine, but with limited effectiveness. One three-month doubleblind study in 55 patients found that high doses of ribaflavin (400 mg/day) were more effective than placebo in preventing migraine (Schoenen J, et al: *Neurology* 1998; 50:466).

CONCLUSION—An analgesic may be effective for treatment of mild to moderate migraine. A triptan or dihydroergotamine is the drug of choice for treatment of moderate to severe migraine headache; the injectable and nasal spray forms of sumatriptan have a faster onset of action than the oral form of sumatriptan or any of the new triptans. A beta-blocker is the best established drug for prevention of migraine attacks.

Flu Vaccination Decreases Relative Morbidity Risk for People with Diabetes

People with diabetes are more likely to die from complications of influenza than people without hyperglycemia. From 1985 through 1987, national surveys on the health and mortality of the U.S. civilian population concluded that people with diabetes are about three times more likely than people without diabetes to die from flu and pneumonia-related complications. Each year, 10,000 to 30,000 people with diabetes are six times more likely than people without diabetes to be hospitalized, and their death rates may increase 5% to 15%. This risk is particularly high when additional risk factors such as cardiovascular disease and kidney disease are present.

It is estimated that immunizations could prevent up to 80% of deaths associated with the flu, yet nearly two in three adults with diabetes do not get a simple, safe flu shot. Aggressive efforts need to be taken to increase influenza immunization levels among people with diabetes in order to decrease flu-related morbidity and the number of preventable deaths.

Typically, physician-regulated diabetes care emphasizes aggressive control of the disease to retard the onset and progression of long-term complications affecting the eyes, kidney, and cardiovascular, and nervous systems. Concentration may be only on diabetes itself, and not on the overall health of the patient. As a result, we may overlook general preventive measures, such as flu shots, that we would utilize with our patients without diabetes.

The Centers for Disease Control is launching a national awareness campaign this fall to encourage people with diabetes to get a flu shot before flu season, which is generally November through March. We also recommend a pneumococcal vaccine for people with diabetes. Nationally representative data suggest that less than on in six persons with diabetes are immunized against pneumococcal pneumonia.

You can help by including influenza and pneumonia vaccinations as part of a regular diabetes management program. Please encourage your patients to be vaccinated to protect themselves from these preventable risks and “take control of their diabetes.”

Frank Vinicor, M.D., M.P.H.
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Centers for Disease Control and Prevention

Guest Editorial

The Role of the Primary Pediatrician When a Child Dies

The death of a child often occurs in a hospital or emergency department. Parents and other family members receive varying degrees of support from consultants, attending physicians, house officers, emergency department personnel, nurses, social workers, and clergy. After the death of the child a family returns home, which is often at a distance from the hospital. The supportive relationship with hospital personnel usually terminates.

A primary pediatrician, particularly if there is a prior relationship with a family, can provide important support at this tragic moment. The extent of a physician's involvement depends on her ability to bear the stress of working with adults and children suffering the loss of a beloved family member and her familiarity with the normal process of grieving.

The pediatrician who appears at the hospital a few minutes after the death of a child, attends a wake or funeral, visits the home, or sends a handwritten condolence note demonstrates his concern for the family at this sad moment. Adolescents who attend a preparatory school or college away from their community appreciate receiving a note, preferably handwritten, from their physician a few weeks after they return to school.

A stillbirth or neonatal death requires a family to abandon their precious fantasies of what they hoped their child might be like in the future. Parents benefit by viewing and holding the lifeless infant. Many parents who decline this opportunity often regret their decision later on. A mother stated six weeks after her infant's death, "I couldn't mourn right! If only I had a few minutes to cuddle and hold my baby, even though she was not alive, it would be easier for me to deal now with her death."

The death of a young family member necessitates that adults and children withdraw their attachment as well as relinquish their dreams of what the child might have achieved in adult life. The living children often experience additional loss because parents are preoccupied with their own grief and have a diminished ability to nurture their children at this sad moment.

A pediatrician can suggest ways of helping children cope with this tragic experience. Children as young as three years, particularly when they have already experienced the death of a pet, may have an understanding of the concept of death. A three-year-old nursery-school child commented with solemnity as he stroked the body of a guinea pig discovered to be dead when school opened, "What's in him can't come out any more!"

Explanation that the individual is "no longer," "not moving," "not eating," and "just resting" helps a child grasp the concept of death. However, understanding the concept of "being dead" is only the initial phase as a child struggles to deal with the loss of a loved one. Care must be taken to avoid suggesting the deceased person "went to sleep forever." This explanation may create undue fears in children that they might die while asleep.

It is important to choose words carefully when explaining to a child what happens to a person after death. One should be honest in discussing one's beliefs. The concept of an afterlife is difficult for children to comprehend. In a family with firm convictions about a life hereafter, a child may think of heaven as a place from which people can return or at least telephone, or send a message by postal service or e-mail!

An adult may state, "The body rests in a special place. I like to believe that the spirit, those things we love about that person, rests in a place called heaven, far away, where there's no pain, hunger, or suffering."

If adults are uncertain about their beliefs they may comment, "I don't know exactly what I believe. I know that some people, many of your friends and their parents, believe that when a person dies, the spirit, the part of them we loved a great deal, rests in a place called heaven, far away."

Presenting beliefs in these simple terms prepares children to deal with the confusion when friends whose families have firm beliefs discuss the idea of a life hereafter. A pediatrician should advise parents to notify a child's teachers that the death of an important person in the child's life has taken place. This will enable them to support the child when he or she returns to school.

Parents often seek advice from their pediatrician as to whether a child should attend the funeral. Children should be encouraged to decide for themselves whether they wish to be present at this final goodbye. Some children find the gathering of relatives and friends and the service supportive while other children consider it too painful and prefer to remain at home with a trusted adult.

Parents preoccupied with their own suffering during a funeral may have little energy to support a grieving child. It is important that a child be accompanied by an adult with whom he or she is familiar. There is nothing as sad as observing a child alone during a service when family members are preoccupied with their own anguished feelings.

When a child asks later on whether the loved one will return, one can help the child deal with reality by saying, "You remember we said goodbye at the funeral. We will all miss him very much. We must remember all the good times we had with him when he was alive."

A parent may burst into tears at this moment. This expression of a parent's sadness communicates to children that they are not alone in their grieving. One cannot hope to prevent children from being sad! One needs to comfort them in their distress as they adjust to the loss of someone they loved and were loved by. Children may ask to visit the cemetery where the individual is buried. The fresh grave often helps a child begin to accept the permanence of the loss.

Pediatricians often meet with a bereaved family following the death of a child. This conference usually is welcomed. It provides opportunity for parents to talk about their feelings about the child's illness and death and to review autopsy findings, if available.

One should ask how the adults and children are faring at this difficult moment. Adults are often ill prepared for the exhaustion and bodily aches that commonly occur as one adapts to the loss of a beloved family member.

Bereaved children and adolescents frequently express concern about bodily complaints or symptoms associated with minor illnesses. They may be frightened that they might die. Frequently children will request an appointment with their physician. Older children and adolescents often telephone their physician directly with their concerns. It is important to respect a child's concerns and offer a prompt appointment for an examination. This visit usually is reassuring to both parents and children. One must bear in mind, of course, that grieving adults and children may develop significant ailments.

A 16-year-old girl who telephoned for an appointment a week after the death of her beloved grandfather, when told her examination results were normal, commented, "I knew that my heavy feelings in my chest weren't really heart disease. But I needed to see you and have you listen to my heart and tell me that I was OK."

A primary pediatrician has a unique opportunity to support adults and children as they experience the death of a loved one. It fulfills the most important role of a pediatrician; that is, to enhance the capacities of parents and children to meet stresses in their lives as effectively as possible.

Morris A. Wessel, M.D.
New Haven

Commentaries

Journal

Internship at Rush Presbyterian St. Luke's in 1979 seems so long ago. Call was every 2nd, 3rd, or 4th night depending on the ward assignment. I remember little of that year except working and not sleeping. I came to rely on the residents supervising me; one had a photographic memory. I identified the medical problems of our patients admitted to our ward. She knew the page in Harrison's *Principles of Internal Medicine* to quote from to help me with the work-up and treatment. I like to remember another resident noted for his pronouncements. "When it's your pain, it's your pain. When it's your time, it's your time."

I was reminded of that on a busy holiday weekend call. It was 8 P.M. on Labor Day and I was seeing my 10th admission. This 98-year-old lady residing in a nursing home had tripped on her walker and sustained a right hip fracture. I was called to clear her for surgery. Her devoted family had just left but they were clear that we would respect her wishes of do not resuscitate (DNR) and do not intubate (DNI). They wanted her hip operated so she could have the chance to walk again and not be bed-ridden.

I saw an elderly lady complaining of being cold. She knew only her name. She had removed her oxygen, and the IV line had disconnected during her transfer to the orthopedics floor from the emergency room. She had received two doses of morphine 3 mg IV for pain in the emergency room. I took her blood pressure only to discover that it was palpable only at 80. Her temperature was 97°. Her pulse was irregular at about 110. I called for the nurses and respiratory therapy. Oxygen was given with a mask which she promptly took off. Her O_2 saturation was only in the 80s. She received wide open IVs of normal saline until she developed some crackles in her lungs, and the rate was then decreased. There was no change in her blood pressure. I left at 9:30 P.M. unsure whether she would make it overnight.

At 6 A.M. the following morning, I returned to find that her systolic blood pressure was palpable at only 50. Little had changed. I gave her digoxin for atrial fibrillation and IV antibiotics. She complained of mild discomfort in her right hip. I called the family for permission to transfuse her as bleeding might be contributing to her hypotension. They would not give permission. She had made her wishes clear when she had an episode of upper gastrointestinal bleeding earlier in the year and refused a transfusion. I then asked her family to consider sending her back to the nrusing home for comfort measures as surgery was now out of the question with her hypotension.

At 4 P.M. that day, the patient's grand-niece came to see her. "You will be more comfortable if you agree to a transfusion." She finally gave her consent. She was transferred to the medical intensive care unit and transfused. Her blood pressure came up to 120/80. She allowed the oxygen and her O_2 saturation was now in the 90s. She did not need any pressors and she was voiding well. She was oriented and appeared warm and comfortable. I prepared myself for the consequences of 20 hours of hypotension and searched for any neurological, cardiac, or renal problems, but so far there were none. She was operated on the following day for her hip fracture. The next day her vital signs were stable. She knew her name but not the date or the place. Her physical examination was unchanged. The nurse reported short-term memory impairment as she had asked the same question 10 or more times.

I shook my head in wonder that she had tolerated 20 hours of hypotension. I have taken care of younger patients who would have had renal failure, a heart attack, or hypoxic encephalopathy after only a few hours of hypoxia and hypotension. Was this 98-year-old lady showing me a physiologic mechanism at work not yet discovered?

The family and I had respected her wishes. As I said good-bye, she smiled and confided "I won't be living much longer." "You should try for 100," I replied. She was to go back to the nursing home for rehabilitation.

I was reminded again my residents saying. "When it's your time, it's your time." Not for this lady, as her family may enjoy the blessings of her company for awhile yet.

The week later, I completed a survey on my views of physician-assisted suicide for the University of Connecticut School of Medicine. I kept thinking of this lady as I answered the questions. Early in her course, it would have been so easy to make the judgment that her prognosis was grim and her life was over and give her some medicine for comfort and let nature take its course. And what if her family had requested that she be put out of her misery? Had I incurred unwanted financial expense for society by managing her this way? What if she lived only another week or month? The treatment, except for the hip pinning, that she received hardly could be called high technology, just intravenous fluids, digoxin, antibiotics, transfusion, and oxygen. Who decides what treatment to give and what to withhold? When is a person's life over and not worth any attempt? I only know that for that patient I was grateful to have had the privilege of caring for her the way I had been taught. Then I waited to see what the future had in store for her, and to my surprise, it was not death but life.

Maria N. C. Stack, M.D.
Cheshire

Survey of Retired Fairfield County Physicians

Do physicians retire at an earlier age today than they did in years past? This question prompted a recent survey of the retired members of the Fairfield County Medical Association. One hundred thirty-six of 335 surveys were returned for a response rate of 41%. In addition to their age, date of retirement, and specialty, retired physicians were asked about their former practices, their reasons for leaving the clinical practice of medicine, as well as information about their postretirement activities.

Survey results were tabulated for physicians who retired between the years 1977 and 1998 based on primary (Fairfield County, Conn.) office location as follows:

	No. of respondents	*Percentage of total*
Bridgeport	43	32
Norwalk	26	19
Stamford	18	13
Greenwich	16	12
Danbury	10	7
Other	23	17
	136	**100%**

Forty-eight percent of the respondents were primary-care physicians and the balance were specialists. The average retirement age of responding physicians was 69.

When comparing age of retirement by specialty, the survey indicated that with Dermatology, Family Practice, Psychiatry, Radiology, Neurosurgery, and Emergency Medicine the age of retirement ranged from 70 to 74. At the other end of the spectrum with Anesthesiology, General Surgery, Orthopedics, and Ophthalmology the age of retirement ranged from 64 to 67.

When asked for the reason(s) for retiring, 53% of the respondents indicated that age was the primary reason. The second, not surprisingly, was the demands made by insurance companies. A decline in personal health, professional "burnout," and a fully-funded retirement plan rounded out the list.

The survey results indicated that physicians who retired "early" (64 to 67 years of age) were generally from group practices, whereas, those retiring "later" retired from solo practices.

Forty-three percent of the physicians implemented semi-retirement strategies prior to leaving the clinical practice of medicine. Reduction of office hours was a popular strategy regardless of specialty. Primary-care physicians often limited the number of new patients seen, and surgeons stopped taking emergency room call.

The survey included questions regarding postretirement activities. Fifty-five respondents (41%) remain active in medicine by either volunteering their time or performing reimbursed medical services. Twenty-four respondents (18%) perform medical pro-bono work. These physicians almost always say they miss the clinical practice of medicine and they wish they had not retired so soon from the clinical practice of medicine. Some 50 respondents (37%) perform nonmedical pro-bono work. Less than half of those performing nonmedical pro-bono work miss practicing.

Prior to 1993, the number of physicians who retired because of the administrative demands of insurance companies was negligible. While recognizing that the numbers are small, it appears since 1993, there has been a "significant" increase in the number of doctors who indicated on the survey that the primary reason for retiring was due to administrative hassles with insurance companies.

In conclusion, this survey clearly indicates that members are not retiring at an early age, assuming one would agree that 69 is not an early age for retirement. Clearly, managed care seems to be exerting its influence in that since 1993 physicians who retired after that time indicated that administrative demands of insurance companies had a definite influence in their decision to retire. Many of these same physicians noted how difficult it was to leave a profession to which they had dedicated so much of their life. On a more positive note, continued involvement in postretirement activities brings benefit to the people of Fairfield County and elsewhere as these professionals use their skills in both clinical and nonclinical settings as a means of continuing to show their concern for mankind.

Fairfield County Medical Association

50 Years Ago

From *The Connecticut State Medical Journal*

November 1948

World Medical Association Second Annual Assembly, Geneva, Switzerland

CREIGHTON BARKER, M.D., *New Haven*

THE Second Annual Assembly of the World Medical Association was held in Geneva, September 8, 9, 10, and 11, 1948. Delegates were present from Australia, Austria, Belgium, Bulgaria, Canada, China, Cuba, Denmark, Eire, France, Great Britain, Ireland, India, Italy, Luxembourg, Netherlands, Norway, Pakistan, Palestine (Jewish), Peru, Philippines, Spain, Sweden, Switzerland, Turkey, United States. Observers were also present from the World Health Organization, the American Medical Women's Association, and the International Association of Women in Medicine. The delegates from the United States were Roscoe L. Sensenich, South Bend, Indiana, president of the American Medical Association; Elmer L. Henderson, Louisville, Kentucky, chairman of the Board of Trustees of the American Medical Association; and alternate delegates, John W. Cline, San Francisco; Creighton Barker, New Haven. Morris Fishbein, editor of the *Journal* of *the American Medical Association,* attended also as an observer.

The meetings of the Assembly were held in the House of Cantonal Representatives in the ancient Town Hall in Geneva. This building is unique in that it has no stairways to its four floors, but inclined paved ramps up which the good and well-fed statesmen of the Canton of Geneva rode on donkeys to get to the halls of legislature.

Professor Doctor Eugene Marquis of Rennes, France, presided at the meetings and the Secretariat was headed by Louis Bauer, Hempstead, New York, who is the Secretary-General of the Association. Dr. Bauer is also a trustee of the American Medical Association. The sessions were carried on in the three official languages of the Assembly, English, French and Spanish. This was not as complicated as it sounds. All remarks and discussion originating in any language were translated into the other two languages. The official interpreter was Dr. Leon Gerin-Lajole of Montreal, Canada, formerly president of the Canadian Medical Association and professor of gynecology at the University of Montreal. He was assisted by two young Swiss women; one of them moved around from French to English to Spanish with the utmost ease and at one point, when a question arose, she went over into Italian to clarify it. Because of the frequency of international conferences in Geneva—perhaps there are more there than any other city—these polylingual people are common.

The Federation des Medecins Suisse acted as official hosts for the Assembly and the elaborate local arrangements and entertainment were made by the Medical Association of the Canton of Geneva.

The purposes of the World Medical Association are: (1) To promote closer ties among the national medical organizations and among the doctors of the world by personal contact and all other means available. (2) To maintain the honor and protect the interests of the medical profession. (3) To study and report on the professional problems which confront the medical profession in the different countries. (4) To organize an exchange of information on matters of interest to the medical profession. (5) To establish relations with, and to present the view of the medical profession to, the World Health Organization, UNESCO, and other appropriate bodies. (6) To assist all peoples of the world to attain the highest possible level of health. (7) To promote world peace and human freedom.

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The agenda for the meetings included many matters of international medical interest and it was pleasing to see how little variation there was in the thinking and sentiment of the representatives from the many countries. The first major item to be considered was the approval of an international pledge in medicine that might be called a brief and modern Hippocratic Oath. However, this had to be called a pledge because there are countries where the meaning of the word oath is at variance with that usually accepted. There was debate over some of the points in this pledge, but finally it was accepted. It is to be called a Declaration of Geneva and says:

"At the time of being admitted as Member of the Medical Profession:

"I solemnly pledge myself to consecrate my life to the service of humanity;

"I will give to my teachers the respect and gratitude which is their due;

"I will practice my profession with conscience and dignity;

"The health of my patient will be my first consideration;

"I will respect the secrets which are confided in me;

"I will maintain by all the means in my power, the honor and the noble traditions of the medical profession;

"My colleagues will be my brothers;

"I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;

"I will maintain the utmost respect for human life, from the time of conception; even under threat, I will not use any medical knowledge contrary to the laws of humanity.

"I make these promises solemnly, freely and upon my honor."

Reports were presented on worldwide studies concerning, "The Status of the Medical Profession in Twenty-Three Countries," "The Advertisement of Patent Medicines," "Proposals Relative to Universal Medical Qualifications" (the impracticability of this was unanimously agreed to), "Unqualified Medical Practice," "Postgraduate Medical Education," "The Training of Specialists," "An International Code of Medical Ethics," and "Social Security and the Operation of National Health Insurance."

It was this last subject, National Health Insurance, which came in for the longest and the most detailed discussion and debate. There could be no question in any one's mind who heard what these people from all over the world had to say, that the lot of physicians in national health insurance countries was far from happy and, in spite of the impressive fact that each of them was trying to render the best possible service to his people, they knew in their hearts that in the system under which they worked the quality of medical care had deteriorated. Finally a twelve point statement was written and adopted. It sets forth what the medical profession of the world thinks should be the rights of physicians in their relation to politically manipulated systems of medical care, and says that whenever medical care is provided as part of Social Security the following principles should govern:

1. Freedom of choice of physician by the patient. Liberty of physician to choose patient except in cases of urgency or humanitarianism.

2. No intervention of third party between physician and patient.

3. Where medical service is to be submitted to control, this control should be exercised by physicians.

4. Freedom of choice of hospital by patient.

5. Freedom of the physician to choose the location and type of his practice.

6. No restriction of medication or mode of treatment by physician except in case of abuse.

7. Appropriate representation of medical profession in every official body dealing with medical care.

8. It is not in the public interest that physicians should be full time salaried servants of the government or Social Security bodies.

9. Remuneration of medical services ought not to depend directly on the financial condition of the insurance organization.

10. Any Social Security or insurance plan must be open to the participation of any licensed physician, and no physician should be compelled to participate if he does not wish to do so.

11. Compulsory health insurance plans should cover only those persons who are unable to make their own arrangements for medical care.

12. There shall be no exploitation of the physician, the physician's services or the public by any person or organization.

Representatives of a few countries were hopeless in their feeling that some of the points could ever prevail in their countries because already political domination and control of medicine had gone so far that the way could not be retraced.

There was no official consideration of the National Health Act of Great Britain that went into effect on July 5, this year, but there were many opportunities to discuss it with the British representatives. Mostly, they said, that the time of operation had been too short to make any valid observation, yet one could not help but note a tone of wan skepticism in all they had to say. Financially, the British physician may be as well, perhaps better off than he was before, but the amount of work which he has to do, the number of patients he has to see, since he has no choice whether he sees them or not, is staggering. The faults of mass social medicine which have been emphasized so vigorously by thoughtful and well informed persons in America become obvious in discussions with colleagues who work under such systems.

Provision was made for the establishment of a quarterly journal of international medicine. It will be published largely in English and its contents abstracted in French and Spanish, but original contributions will be published in the language of the country of their source. Morris Fishbein is to be the editor of this quarterly.

The World Health Organization, a section of the United Nations, has established formal liaison with the World Medical Association, the first of such relationships to be entered into. Dr. J. Maystre, Geneva, has been designated the liaison official. Dr. Charles Hill, secretary of the British Medical Association, was elected president-elect of the World Medical Association. The 1949 Annual Session will be held in London, the interim meeting of the Council in Madrid, and the 1950 General Assembly in the United States.

The World Medical Association has no illusions with respect to its ability to solve all the problems of mankind, but the organization does hold great promise and recognizes the opportunity that it has to assist all peoples of the world, irrespective of race, color or creed, to attain the highest level of health. In so doing there must be another result, to cement together more closely the elements of friendship and understanding for physicians everywhere.

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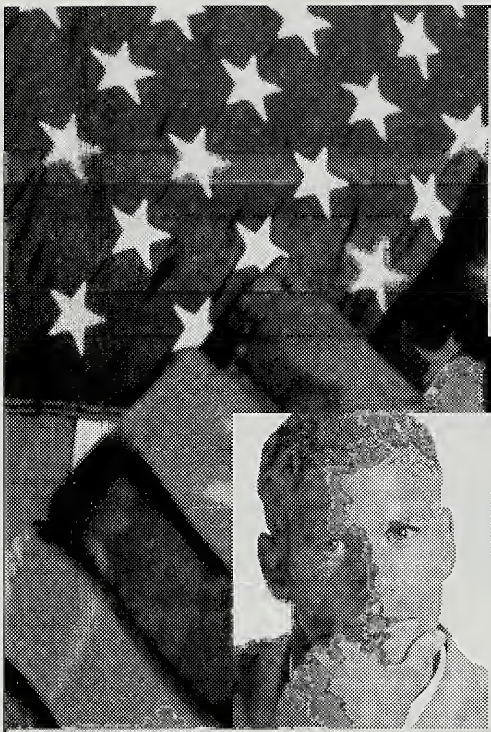

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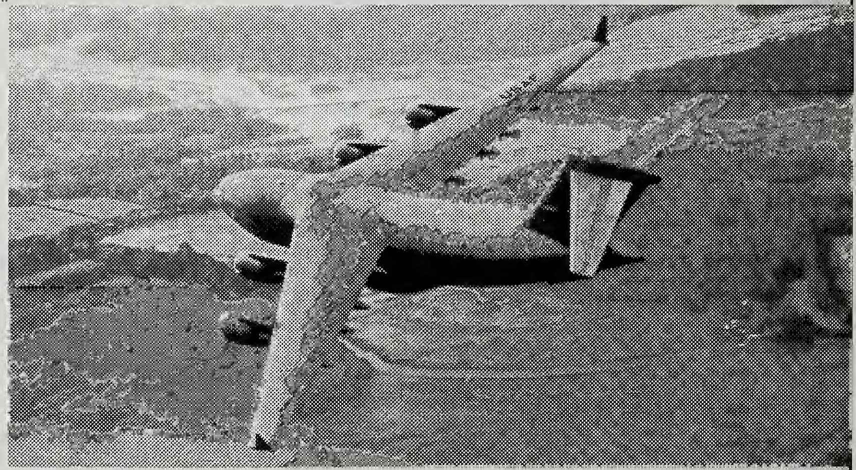

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In Memoriam: Kathleen McShane, M.D., 1950–1998

(The following remarks were delivered by Dr. Czarsty at a memorial service for Dr. McShane on 30 October 1998. Dr. McShane died in a car accident on 21 October 1998.)

When Bruce asked me to speak, today, my first reaction was the usual one. "Oh, boy, what am I going to say?" I thought quite awhile about Kate and the times and experiences we shared. I thought about Kate and her involvement in the Connecticut Academy of Family Physicians. I remembered some of the stories I had heard her tell about her family. I remembered some of the stories she told about the families for whom she cared in her practice. The word "family" kept coming back to me. I tried to avoid it as I thought it might be too obvious a metaphor, but I couldn't avoid it. Kate was at the center of several families; her life with Bruce, her own family, Bruce's family, her patients and their families, and her extended family in the Connecticut Academy of Family Physicians.

She was marvelously adept at keeping all of those families front and center. While responding to the demands of a busy practice, she was able to care for her ill father in her home. While she and Bruce were moving into a new home, she was able to balance those responsibilities with her involvement in the Connecticut Academy and organized medicine.

Kate was somewhat modest about her accomplishments so let me tell you about some of them. She was the second woman president of the Connecticut Academy of Family Physicians, the first in many years. She was the first woman to become an alternate delegate to the American Academy of Family Physicians. She led our political action committee and her last public speech, a week ago Wednesday, was an impassioned plea for the cause. She represented Connecticut several times at the American Academy's Conference for Women, Minorities, and New Physicians. She was a strong voice in the national women's caucus. Back home, for many years, she moderated the annual luncheon for women, minorities, and new physicians. She also found the time to serve as president of the Middlesex County Medical Association and to play an active role in the Department of Family Medicine at Middlesex Hospital. Kate served six years on the Editorial Board of the Core Content Review of Family Medicine, the pre-eminent home self-study course in its field.

Service on the Core Content Board is when we family physicians become extended family to each other. The Board meets three times a year, out of state. We travel together. We are locked up together in conference rooms for days at a time. And, yes, we take time to enjoy ourselves wherever we happen to be. While Kate and the rest of us were in those conference rooms, Bruce was the usually the ringleader of the spouses. We always looked forward to the end of the day when we would hear the stories of their adventures. In fact, Kate often joked that the only reason we let her come to the meetings was so that she would bring Bruce along. There was no mistaking that it was a joke, though. Kate has been an integral part of our group for a long time.

We are gathered here, today, because of a life tragically foreshortened, a catastrophe too terrible to comprehend. When disaster strikes, and after the initial shock wears off, the inevitable question we ask is, "What kind of God would let this happen?" That line of questioning often leads to anger at God and turning away from God. Many take the attitude that, if all we can expect from God is affliction, how can God expect us to pray for strength in our time of need. I would suggest that if we only recognize God in our lives in times of adversity, we are probably not looking hard enough. Let us exalt the Creator-God who gave Kate to her parents and siblings and then, later, to us. Let us praise the Nurturer-God who watched over Kate as she grew and matured. Let us glorify the Mother-God who gave Kate her healing touch. Let us honor the Father-God who gave Kate the strength to excel in a profession in which women are not always accepted. Finally, let us thank the Loving-God for giving Kate and Bruce to each other.

Continued on next page

John Glenn left this planet yesterday. I envy him for his ability to rocket into the heavens and return to tell us about them. I believe Kate is in Heaven with her Creator. From now on we will only see her with our hearts instead of our eyes. Let us be guided by our hearts and by our memories of Kate to strengthen the bonds within our families. Let the joy we shared in Kate allow us to be with each other in our times of need. Bruce, on behalf of all of us in the Connecticut Academy, I just want to remind you that you are family to us and we will be there for you when you need us.

In closing, I would like to read two verses of an old hymn which I find comforting in times like these.

When peace, like a river, attendeth my way,
when sorrows like sea billows roll;
whatever my lot, thou hast taught me to say,
It is well, it is well with my soul.

And, Lord, haste the day when my faith shall be sight,
the clouds be rolled back as a scroll;
the trump shall resound, and the Lord shall descend,
even so, it is well with my soul.

Craig W. Czarsty, M.D.
President

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Twilight of the Heroes?

ROBERT U. MASSEY, M.D.

"THE Heroic Physician in Literature: Can the Tradition Continue?" was the title of an address given by Anne Hudson Jones at the American Osler Society Meeting almost six years ago. The heroes she spoke of were doctors in literary works, the very ones that affected many of us during our more plastic pre-medical school days: Tertius Lydgate in George Eliot's *Middlemarch*, Max Gottlieb in Sinclair Lewis's *Arrowsmith*, and several others. In passing she recalled A.J. Cronin's *The Citadel.* The hero physician in this 1937 novel was Andrew Manson. After I had finished reading about this heroic young Scots physician, I recall wishing that someday I might be Manson, bringing modern medicine to some remote place. During that same summer I read, Vallery-Radot's *The Life of Pasteur* and Eve Curie's *Madame Curie.* My personal pantheon was taking shape.

Encounters with Lydgate and Gottlieb were to come later. I came to know more about Sinclair Lewis, his association with the University of Michigan, and how *Arrowsmith's* Max Gottlieb was drawn from the character of Frederick George Novy, the bacteriologist at Ann Arbor in the early decades of this century. It happened that my father's cardiologist was Novy's son, and I believe the two of them spent more time talking about Sinclair Lewis and Dr. Arrowsmith than about my father's ventricular septal defect.

Professor Jones analyses the attributes of the heroic physician in literature, "great talent, a keen intellect employed in the rigorous search for truth, and a savage disregard for material rewards and earthly honors," and "[o]ne more—compassion...."

But heroes to work their magic should be drawn from real life—they may be long dead, but they must at one time have drawn breath from the very air that we breath, have walked on soil and labored in places very like our own, faced all the trials and limits of our human condition. For many in my generation, and Dr. Arrowsmith's, William Osler was one, perhaps the greatest, of them all. He was spoken of frequently in medical school, we used his textbook—mine was the 15th edition, edited by Henry Christian. It still carried the dedication to William Arthur Johnson, priest of the parish of Weston, Ontario; James Bovell of the Toronto School of Medicine, and Robert Palmer Howard, Dean and Professor at McGill. My wife gave me a copy of Harvey Cushing's *The Life of Sir William Osler* during my third year in medical school. We once drove into Ontario looking for his birthplace at Bond Head near Dundas—it was only about 150 miles from Detroit—but no one we asked had ever heard of him. But of course, heroes are heroic only to a few.

The word "hero" sounds Greek, and indeed it is: *heros*, a warrior and others of the Trojan age, including even leeches and minstrels, superior to anyone living since, including demigods, according to my lexicon those offspring of one divine parent such as Asklepios, Achilles, Hercules. Professor Jones places the heroic age in medicine, or at least as represented in literature, as roughly between 1850 and 1950. Since midcentury the notion of heroism in medicine has been in danger, if not in decline. She names four likely reasons:

> [F]irst the remarkable success of medical technology in keeping bodies alive indefinitely (with the concomitant high costs); second the continuing impotence of medicine to cure many diseases—represented most powerfully by AIDS; third, the social changes in gender roles; and, fourth, the assault on Western values by an increasingly multicultural population.

I would add a fifth: how could a member of the *health-care industry*, or a *health provider*, a mere technician ever be heroic? "Ironically," Jones observed, "in a time when medical miracles are commonplace, physicians in literature are oddly unheroic. The heroic tradition has been displaced by satire, more bitter now than it was in the earlier comic tradition."

Thomas Carlyle, in his *On Heroes, Hero-Worship, and the Heroic in History,* written over 150 years ago, did not include physicians, only gods, prophets, poets, priests, men of letters, and kings. William Osler, 54 years younger than Carlyle, had five portraits over his mantel, both in Baltimore and at Oxford: his three medical heroes, Linacre, Sydenham, and Harvey, as well as the Baltimore physician Horatio C. Wood, who was influential in his Hopkins appointment, and John Henry, Cardinal Newman. Speak of Linacre, Sydenham, Harvey, even Osler or Halsted, to almost any three medical students or residents today and their looks would be uncomprehending. I've tried it.

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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This Month's Reading in Review

TIMOTHY B. NORBECK

"State health insurance regulators are reporting surging numbers of formal complaints from patients and doctors against health insurers, primarily health maintenance organizations. What troubles the commissioners more than the volume of complaints is a broad shift in the nature of them. Disputes with insurers have changed from conflicts over who should pay for care, to conflicts over denials and delays of care and over medication and forms of treatment."

New York Times (11 October 1998)

"That 80% of managed care enrollees are satisfied with their care obscures the views of a less satisfied 10% or 15% who make much use of the organizations. In any health plan, the vast majority are healthy and not using the services. If you're just carrying their card in your pocket, what are you going to complain about?"

An analyst at the Institute for Health Care
Research and Policy at Georgetown University.
New York Times (11 October 1998)

"The future of the managed-care industry depends on public trust and confidence, and the industry has blown that. It's not just patients' horror stories that have eroded public confidence. Skimpy benefits are only part of the problem. The larger problem is that no one knows how well different plans are performing."

Lynn Etheredge, a leading member of the Jackson
Hole Group, which conceived modern-day
managed care. *Newsweek* (28 September 1998)

Allowing patients to sue their health plans when grievance and appeals procedures fail will not result in high rates of litigation, nor will it cost more than pennies per member per month.... That is the conclusion reached by the first retrospective study of health plan lawsuits, and based on the experiences of public insurance programs in California and Colorado, which have long given enrollees that right.... The study was conducted by Coopers & Lybrand for the Kaiser Family Foundation.

Business & Health (September 1998)

"It is time for the scientific community to stop giving alternative medicine a free ride. There cannot be two kinds of medicine—conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation, and testimonials do not substitute for evidence. Alternative treatments should be subjected to scientific testing no less rigorous than that required for conventional treatment."

From an editorial in the *New England Journal of Medicine* (17 September 1998)

"After years of interfering in doctor-patient relations, exacerbating the problem of the uninsured, denying responsibility for medical education and research and rationing health care, health maintenance organizations are refusing to cover the elderly while asking for rate increases. How much more evidence do we need before we realize that managed care is a failed system that should be abandoned?"

A letter to the editor from a New York physician.
New York Times (8 October 1998)

A front-page story reported that "managed care has lost its luster as an industry and as the answer to the nation's health care needs."... The article went on to suggest that managed care "has so far served as a different way to pay for medical care, not a better way to provide it."... And while it has contributed to significant cost savings, it went on to say, those savings "are likely to prove temporary" as coverage is becoming more expensive for small employers.... Managed care also "has shifted many consumers' concern from cost to quality."

New York Times (5 October 1998)

Only In America: In March, a Connecticut teen filed a lawsuit against a truck driver over a 1997 accident in which her passenger was killed as her car ran into a truck.... The truck was legally parked on the side of the road, but the young woman said it was still a nuisance because she had a hard time seeing it in the "glaring sunlight."... She is still on probation stemming from a negligent homicide charge in the incident.

America Online (5 October 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

In Response to *The Ethics of Organ Transplantation*

Letter to the Editor: The following is a response to Dr. Blansfield's recent letter (*Conn Med* 1998; 6:367) regarding the ethics of organ transplantation. Having read a number of his other articles regarding "unfair" treatment of drug addicts I feel obliged to respond. Let me begin by stating I had extensive experience in this area as a result of six years working in a state facility for the treatment of alcoholism, drug addiction, and mental illness. During this time I participated in the treatment of thousands of patients. No one was treated unfairly or dehumanized. The entire staff was competent and caring. Numerous patients abused the staff and the use of the facility. Several staff members were hospitalized as a result of injuries inflicted by patients. Patient rights were never infringed on or restricted in any way. At one point the alcohol ward closed due to lack of funding. Virtually overnight the same patients who had been psychiatrically "cleared" for detox (some up to 45 times) were found to be "gravely disabled" mentally and admitted to the psychiatric ward. For many of these clients it proved to be a blessing. Now they were eligible for numerous entitlements including special housing and disability checks. Like most facilities of this type, it was almost always operating at capacity. Thus, bed availability limited access to the psychiatric unit. Numerous "less sick" but potentially more likely to be rehabilitated patients were denied access because "more sick" [translation: multiple visits] patients were occupying the available beds. Now I come to the point of this letter.

Whether it is treatment for alcohol, drugs, mental illness, or a liver transplant, there are just not enough to go around. Medical care in all forms has reached crisis proportions. Like it or not some hard decisions will have to be made regarding eligibility for these programs. Tacitly, it is already taking place due to limited beds in rehabilitation and mental care facilities or lists for transplantation. If resources were unlimited it would be hard to justify denying anyone every option to improve her quality of life regardless of the life she chooses to lead. However, resources are not unlimited. Making lists and ranking needs is a necessity. Before I become the victim of a diatribe of rhetoric on the unfairness of the system toward alcoholics and drug addicts consider this everyday example. Countless diabetics spend their entire lives regulating their diet, their insulin dosage, and taking an active role in the management of their disease. If diabetics moaned "I have a disease" and used this excuse to remove themselves from responsibility for their own well being, where would they be? The linchpin of treatment for alcoholism is accepting responsibility for one's actions not blaming it "on a disease." A written contract for abstinence is unenforceable and unconstitutional (made under duress).

Both diabetes and alcoholism are chronic conditions requiring a lifetime of management. Diabetics slip and are hospitalized for dietary indiscretions or judgment lapses. The same is true for alcoholics. Education and motivation separate those who successfully come to grips with their disease and those who do not. To simply accept alcoholism as a neuronal defect with inevitable relapses downplays the significance of cognitive behavioral therapy and A.A. Millions of alcoholics are getting on with their lives "one day at a time." If alcoholism is purely a "chemical imbalance" then we should close all the detox facilities and abandon "useless" counseling including A.A. After all, these patients are doomed by their brain disease. Fortunately, as countless "reformed" alcoholics will attest, there is hope. However, for every "reformed alcoholic" there are dozens who put no effort into maintaining sobriety. I do not doubt for a moment that these individuals have a disease but it is too enabling to blame their outcome solely on the disease itself. We need a fundamentally different approach to the relapsing alcoholic. Until then tremendous amounts of limited resources are being wasted on ineffective treatment. This is where public sympathy runs dry. It is difficult to pity self indulgence or repeatedly forgive relapses when there is no motivation to change. Regarding the ethics of lists, let me ask: Who is the better candidate for the next liver? The lifetime alcoholic or the child with congenital liver disease? Cirrhosis does not happen overnight. If a cirrhotic patient can not find the strength to stay off alcohol for six months for a second chance at life why should someone else be put aside for their first chance? This is the harsh reality of the situation in the health-care field today. The well is about to run dry. To whom should we give the last drink?

James Marshall, Jr., D.O.
Monroe

In response to Dr. Marshall's letter: I wish to thank Dr. Marshall for his comments regarding alcoholic liver disease and the issue of who gets a transplant. I can understand his frustration concerning the relapsing chronic alcoholic who just doesn't seem to be able to remain abstinent. This phenomenon was discussed at length by Jefferson A. Singer in his recent book *Message in a Bottle: Stories of Men and Addiction.*

Dr. Marshall states: "The linchpin of treatment for alcoholism is accepting responsibility for one's actions not blaming it 'on a disease.'" Further he says: "It is difficult to pity self indulgence or repeatedly forgive relapses when their is no motivation to change." These statements appear to be based on the belief that alcoholism is primarily a moral and ethical issue that could be resolved by the desire and will to remain abstinent. This approach to chemical dependency is not currently supported by neuroscience.

Alan I. Leshner, Ph.D., Director of the National Institute of Drug Abuse (NIDA) states without reservation: "Addiction as a chronic relapsing disease of the brain is a totally new concept for much of the general public, for many policy makers and, sadly, for many health care professionals." He also said that "addiction must be approached more like other chronic illnesses—such as diabetes and chronic hypertension." He concludes by saying: "Understanding addiction as a brain disease explains in part why historic policy focusing solely on the social or criminal justice aspects of drug use and addiction have been unsuccessful."[1] If this is the case and chronic relapsing alcoholism is the result of neuronal change, then eligibility for organ transplant should be considered on a par with other diseases producing life-threatening liver damage.

Henry N. Blansfield, M.D.
Danbury

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[1] Leshner AI: *ASAM News*. (Jan/Feb.) 1998; 13:1,12.

Simple Truths

Letter to the Editor: Your essay "A Question of Virtue" points in the right direction: to the question, not the answer. Answers may change, but questions endure. The human condition by its mortal nature is a predicament. What remains is ambiguity: "To be or not to be, that is the question."

There seem to be a few simple truths, "truth as old as the hills," which unite us to those who lived and died many centuries ago. Civilization is transmitted by the actions of our parents, combined with written language from ages past. The past is alive in the present, and recreated with each new generation. As Carlyle said, "history is the distillation of rumor." The future is unknowable, except for our common mortality. And so we are left in this imperfect state, marooned in a Universe beyond human comprehension, wondering why there are any truths.

Our philosophers create artificial conceptual schemes that too often obscure the few simple truths we learned as children. Leaders, lawyers, and lobbyists often take advantage of these obscurities. As children, we learn that to tell lies is wrong, showing that we know the truth in our hearts. Of all the divisions of philosophy, ethics, knowledge of the good, is the most elemental. We neglect it at our peril. Can conscience exist in a Universe without purpose? That is the question.

Charles W. Needham, M.D.
Norwalk

In Response to Dr. Koenig's Letter to the Editor, "My Daddy, M.D."

Letter to the Editor: The child's poem, *My Daddy, M.D.,* submitted by Allen Koenig and published in the September issue's *Letters to the Editor* alludes to a frequent *faux pas* committed by physicians.

The poem's opening lines are; "Whenever Daddy signs his name, He always writes M.D." According to recent editions of Emily Post's and Charlotte Ford's books on etiquette, one should sign his or her name, without degrees or titles, when using personalized writing material, or when the individual's name and title are typed beneath the signature. Since most physicians use printed letterheads and prescription forms, signing M.D. after one's name is, shall we say, being boorish.

In this era of corporate medicine we physicians should tend to our business etiquette lest all those lofty CEOs of managed-care cartels think doctors "ain't got no culture."

Lee Sataline, M.D
Cheshire

HMOs: Managed-access, Not Care

Letter to the Editor: Why should HMO executives be paid multimillion-dollar salaries? What is the value that they and their companies add to health insurance? Even the federal government operates Medicare for a lower percentage of premium than do most commercial HMOs.

HMOs do not manage care in this state or any other. They manage access. That is, they make their profit by limiting the amount of care their insureds may receive. So far, premiums in Connecticut have been fairly level as the companies squeeze doctors and hospitals. Soon there will be nothing left to squeeze and, at the same time, the number of HMOs in the state will consolidate to four or five. Premiums will again go up at precipitous rates. Remember, the only way the executives justify those huge salaries is by delivering profit to Wall Street.

Profit to Wall Street is the American way, of course. However, if one thinks the price of a new car is too much, he looks for a used one or does without. Is this the way we want health insurance to work? It is already unaffordable for millions of Americans but there is no cheaper alternative. For how many more must it become unaffordable before society says, "enough is enough"?

Craig W. Czarsty, M.D.
Oakville

Editor's note: Dr. Craig W. Czarsty is president of the Connecticut State Medical Society.
Published in the *Republican-American*, Waterbury,
Sunday, 4 October 1998

In Response to "Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?"

Letter to the Editor: This is in regard to the article called "Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?" (*Conn Med* 1998; 62:461-4). It seems to me Drs. Welch et al did the wrong study. If they want to evaluate epidural postoperative analgesia they ought to compare it with patient controlled analgesia (PCA) using intravenous morphine. In my experience as both surgeon and patient I have found that nothing compares with intravenous morphine for pain control. Anecdotally, my own personal experience with epidural analgesia after suprapubic prostatectomy was one of the worst experiences of my life.

James M. Dowaliby, M.D., F.A.C.S.
New Haven

In response to Dr. Dowaliby's letter: I agree with Dr. Dowaliby that the most valuable study at the present time would be to compare epidural postoperative anesthesia with PCA. In most of the patients whom I have taken care of that have had epidural anesthesia, the pain control has been quite satisfactory, although admittedly it does not always work.

John P. Welch, M.D.
Hartford

Welcome to the World of Managed-care Submitted to the *Danbury News-Times*

Letter to the Editor: I could only shake my head and smile the other evening when on the Channel 8 news I saw Senator Dodd and a group of senior citizens say how horrible it was that two of the major managed-care companies in Connecticut had announced that they were withdrawing from managed Medicare participation. Their reasoning was that payments from the government for taking care of Medicare patients were too low for them to make a profit. Some of the senior citizens testifying were crying and others were voicing anger. To them, to our elected leaders, and to the rest of the public: welcome to the world of managed-care and welcome to what physicians have known since the beginning of this managed-care revolution nearly 10 years ago.

You see, we physicians have been accepting poor government payment for taking care of our state's elderly for a long time. Do you think that I thought it was fair compensation to be paid $47 to get out of bed at 3:00 A.M. to go take care of a Medicare-covered person in the emergency room? I knew that was not a fair payment, but my fellow physicians and I have done it and still do it because it is what is right. It is what we are ethically bound to do by the Hippocratic Oath, and it is our service to the elderly of our community. But now the physicians are being pushed to the limit. It was one thing to accept ridiculously low compensation from our government to take care of the Medicare population, because at least we knew that no one was making a large profit off of our backs. We could somehow justify it that the government really did not have enough money to pay us, that there was a budget deficit, and that no one was going to raise taxes or increase premiums to meet that deficit.

What has created extreme frustration and even anger among the physician community is when these managed-care insurance companies, who are not our government, compensate us at these ridiculous rates, and then take their profit from your premium and pay executives millions of dollars and reward their shareholders generously. I do not mind getting out of bed at 3:00 A.M. to see somebody in the emergency room and then getting ripped off by my government, but I will be damned if I am going to work for essentially nothing so that some insurance executive and his shareholders can be handsomely rewarded.

My fellow physicians and I during this turmoil have served as advocates for our patients, fighting for their tests, their surgeries, their special treatments, fighting to make sure they receive adequate care from the profit-driven insurance outfits. We write letters, make phone calls, fill out formslose our fight and zeal. It is time that our patients started fighting in this battle, fighting for the physicians who have been on their side trying to maintain the highest level of care in the world. If they don't feel we deserve it, at least they should fight for themselves. They should not sit back while this fine health system is dismantled. The quality, the dedication of the physicians caring for them today may not be available when they are elderly, or their children grow old. This is a critical moment in the history of American medicine; they, our patients, will largely determine the outcome.

For Senator Dodd and those Medicare recipients who were at that meeting on the news, just remember who backed out when there was not enough money to go around. And remember who has been and always will be there when you need them most, your physicians.

Jeffrey I. Gorelick, M.D.
Danbury

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are invited to submit their papers to the *Journal* for consideration. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **Information for Authors**. This is published in most issues of *Connecticut Medicine* or may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Papers prepared on a word processor should be submitted on a diskette along with the hard copy.

Please send them to:

Robert U. Massey, M.D.
Connecticut Medicine
160 St. Ronan Street
New Haven, CT 06511

The Robert U. Massey History of Medicine Society

Upcoming Schedule of Presentations

December 9

Stanley W. Jackson, M.D., Professor Emeritus of Psychiatry and Senior Research Scholar, History of Medicine, Yale University School of Medicine

Eli Todd: A Farmington-New Haven Connection

January 13

Heather Munro Prescott, Ph.D., Associate Professor, Department of History, Central Connecticut University

The White Plague Goes to College

The Robert U. Massey History of Medicine Society is an association of individuals interested in presentations and discussions on the history of medicine. The society seeks to foster an understanding of medicine's history and an appreciation for the cultural and social settings in which medical developments have taken place. The society also seeks to encourage health sciences students to acquire an appreciation for their historical heritage.

The society is affiliated with the University of Connecticut Health Center and is open to those who have an interest in the history of medicine. A roster of members is maintained in the Department of Community Medicine and Health Care. Those who wish to be included on the membership roster should notify this department to be included on the mailing list for society lectures. The willingness of members to present lectures or recommend speakers contributes to the society's ability to maintain community interest and to attract new members.

The society meets the 2nd Wednesday of the month at 5 P.M. in Lecture Room A of the University of Connecticut Health Center. *For further information:* Theo Ungewitter, Department of Community Medicine, University of Connecticut School of Medicine, 263 Farmington Avenue, Farmington, CT 06030-1910; (860) 679-2356; *email:* ungewitter@nso.uchc.edu

BOOK REVIEW

Medical Warrior:
Fighting Corporate Socialized Medicine
by Miguel A. Faria, Jr., M.D., 207 pp, $23.95,
ISBN: 0-9641077-2-4, Macon,
Georgia Hacienda Publishing, 1997.

> The direction in which we are headed today in medicine is plain and simple—corporate socialized medicine —a concept centered around managed care/managed competition, gatekeepers, cost controls, and rationing, obfuscated by the profit motive and sanctioned by government authority.

With these words, Dr. Miguel Faria summarizes the central thesis of this collection of essays. These writings represent much of his editorial output while serving as Editor of the *Journal of the Medical Association of Georgia* from 1993 to 1995, a position that he eventually was asked to relinquish because of his controversial opinions. Many physicians, ethicists, and others have written about the meaning of recent events in American health-care delivery. But here, in one concise volume, Dr. Faria brings together some very critical thinking for all to ponder. And the resulting image that he creates is quite worrisome.

The essays are organized into five major areas—lessons from history, medical ecology, towards collectivism in medicine, the role of public health, and finally managed care, corporate socialized medicine, and medical ethics. Each essay is short, packed with information, and stands well alone. Where these essays occasionally fall short is in their sporadic reliance on events that were current at the time the essays were first written. Unless one is a dedicated student of the recent upheavals in American medicine, many of the events to which Dr. Faria refers with such passion have long faded from the average reader's memory. (This is an important message to the would-be essayist; timelessness is an indispensable part of any essay that is to be of lasting value.) Despite this, the material that he presents in each section is worthy of study.

The passion that Dr. Faria brings to his subject is phenomenal. Much of it no doubt derives from the fact that he came to live in the United States only after escaping with his father from Cuba at age 13. His knowledge of the oppressive restraint inherent in a socialist system was learned first-hand from those who struggled and succeeded in escaping its bonds. He is an astute observer of the techniques by which oppressive governments work to secure control of their citizenry in order to advance governmental power and prestige. He understands how governments succeed in putting favored systems into place, whether they be medical care in ancient Egypt and Babylonia, or the Clinton Health Plan and its pseudo-free-market managed care variant here in present-day America. And he clearly understands how excessive law and regulation always lead to a reduction in the level of care that is given to patients. Indeed, one of the highlights of this collection is the essay "Hammurabi, Defensive Medicine, and Practice Guidelines." In it, Faria shows how the Code of Hammurabi led to the withholding of critical medical treatments from patients in ancient Babylonia and Egypt, lest the treating doctor be subjected to punishment for "unfavorable outcomes." This essay, first published in March 1995, deserves to be revisited by Dr. Faria with the passage of the so-called "fraud and abuse" provision contained in the Kennedy-Kassenbaum legislation (HIPAA) of 1996. It would appear that the latter is indeed our own, modern-day "Code of Hammurabi," designed to curb our would-be collectivized medical care costs by inhibition of physician activities through the use of the threats of severe punishment for certain behaviors and activities!

Dr. Faria devotes a significant amount of time to the question of whether the concept of public health is being misused, particularly in the current medical literature, in order to re-order the practicing physician's focus and ethical orientation from the current "one-to-one" approach to what has been recently called the "one-to-n" population-based approach, which is much more adaptable to collectivist medicine and ideology. He presents some very pointed criticisms of a few revered medical publications that, in his opinion, appear to be collaborating with these efforts to the point of their losing all respect for true peer review and objectivity. Similarly, Faria expends considerable effort criticizing the AMA for "collaborating with the enemy" in order to maintain it's "place in the sun." Unfortunately, in the course of these discussions he also veers far off course into the subjects of the misuse of public health "research" by gun-control advocates and environmental activists. These groups do indeed utilize dubious research models via the public health approach in order to advance their political agendas. But while this criticism is well taken and does dovetail with his criticism of the misuse of public health research in medical population-based studies, much of this material will seem extraneous to most physician readers.

But Faria's greatest contribution through these essays comes in a short work entitled "The Medical Gulag." Starting with Aristotle's teaching that "Acquiescence is the trademark of the slave," Faria goes on to remind us of a remarkable observation made by Alexander Solzhenitsyn. Those prisoners in the Gulag who collaborated with their taskmasters by taking on extra work for extra rations actually received fewer calories in that extra ration than were expended in the additional work that they did in order to obtain it. Thus, those who collaborated with and acquiesced to the demands of their oppressors actually hastened their own demise. I suspect that those physicians who most readily acquiesced to managed care by switching from caring for patients to a system of ever-increasing daily “patient encounters” in return for ever-diminishing remuneration have now started to see the “Gulag effect” in their own practices’ bottom lines!

In summary, *Medical Warrior: Fighting Corporate Socialized Medicine* brings to the practicing physician some hard, practical lessons about medical organization, practice, and most of all, freedom, that must be learned. It is often observed that after the occurrence of traumatic events, people say to those in charge, “Warning signs were there all along, as plain as the nose on your face. Why didn’t you point them out to us?” With the publication of this collection of essays by Dr. Faria, I do not believe that any physician can ever again claim a “lack of warning” about the unique and pernicious brand of Corporate Socialism that American Medicine is in danger of becoming in these waning days of the twentieth century.

Stephen R. Katz, M.D.
President-elect,
Connecticut State Medical Society

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The Harvard Medical School and the Beth Israel Deaconess Medical Center, both of Boston, are seeking participants for a genetic study on aging. Subject candidates are individuals 98 years old and older and their living brothers and sisters who are at least 90. Participants do NOT have to live in the Boston area. Participation is voluntary and free of charge. To help us discover information that could lead to a cure for such devastating diseases as Alzheimer’s disease and cancer, please refer us to any of your patients who may qualify. Call us toll-free at 1-888-333-6327. Thank you for your assistance.

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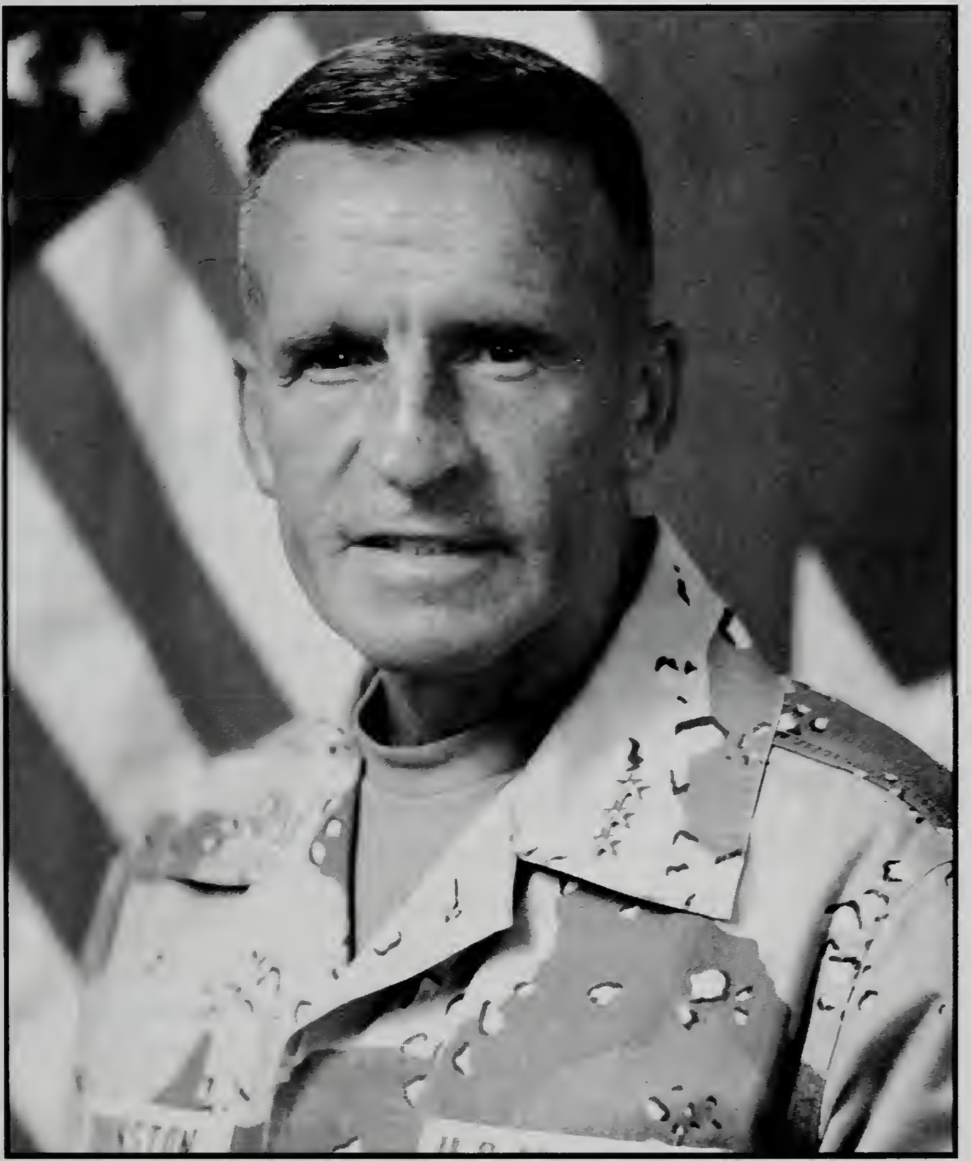

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- The Physician's Role
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- Considerations of Medical Necessity
- Services Available in the Home
- Determining Frequency and Duration
- Criteria for Prolonged Home Care Services
- What to Look for When Choosing a Home Care Organization
- Recognizing Fraudulent Practice
- Patients Rights and Responsibilities
- Community Resources

A physician who is a member of the AMA is entitled to a complimentary copy. Additional copies are $4 each. Orders can be placed by calling (312) 464-5085, or sending a check to:

American Medical Association
Department of Geriatric Health
515 North State Street
Chicago, IL 60610

COMMITTEE SERVICE QUESTIONNAIRE

Connecticut State Medical Society

Early in 1999 the Councilors from the eight constituent county medical associations will assume the responsibility of selecting members of the Society to participate in the various activities of the Society, listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

Executive Director's Office
160 St. Ronan Street
New Haven, CT 06511

Your cooperation will be appreciated.

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- ★ Managed Care Patient Advocacy Committee

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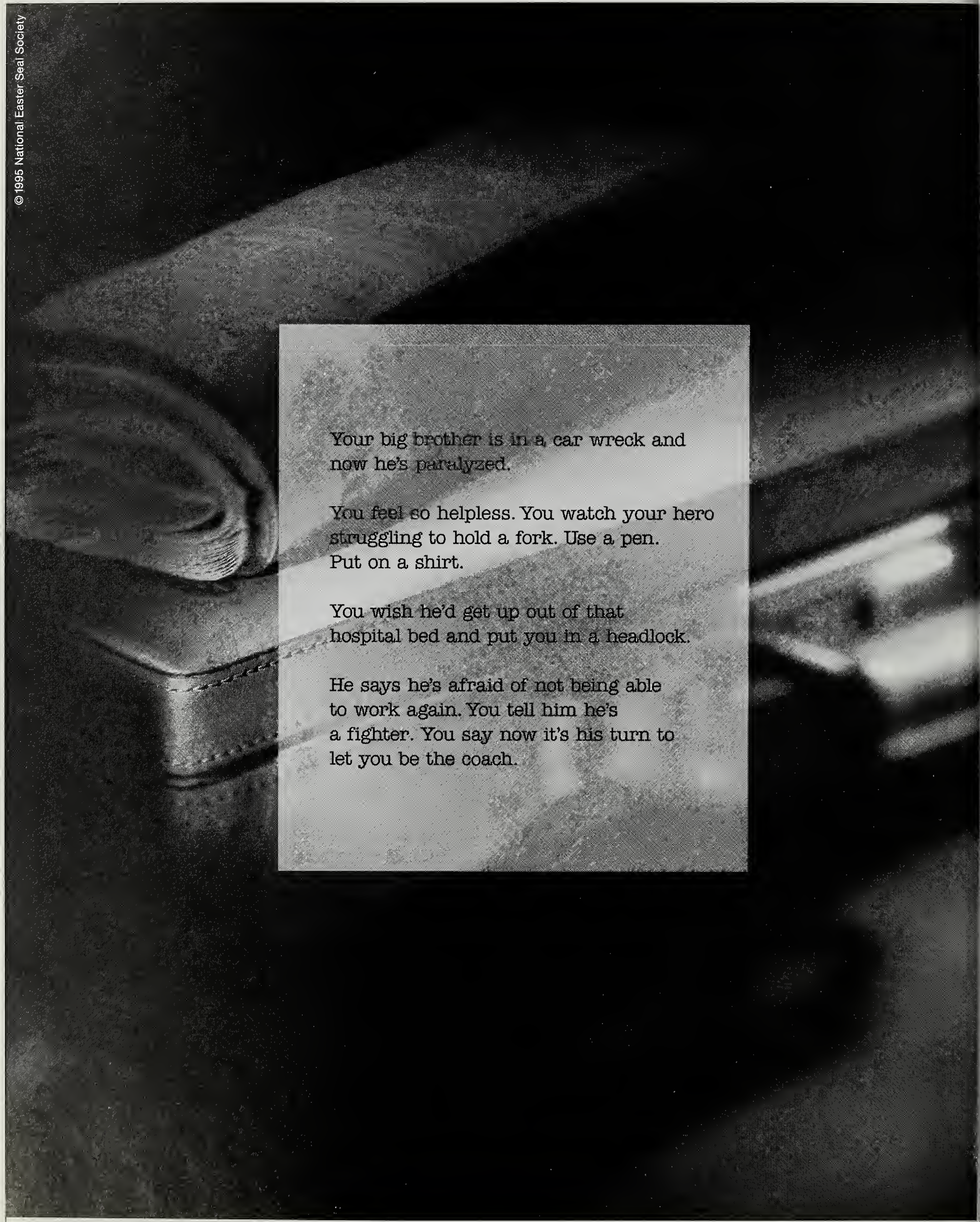

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The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

***Opportunities* should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians inquiring about such *opportunities*.**

***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

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Available October 1998. Licensed in Connecticut. M.D. at Universidad Technologica de Technologica de Santiago, Dominican Republic. Internship and residency at Brookdale Hospital, New York. Fellowship at Kings County Hospital/Long Island College Hospital, New York. Seeking a position in a walk-in, community health or urgent care clinic. Please respond to: Mallick Q. Alam, M.D., 39B Robert Treat Dr., Milford, CT, telephone (203) 882-0638.

INTERNAL MEDICINE

Available January 1999. Licensed in Connecticut. Passed National Boards. American Board certified. M.D. at Tufts University School of Medicine. Internship and residency at the Hospital of St. Raphael. Office based general internist with extensive managed care experience, seeking to join a group or associates practice. Please respond to: Michael F. Collins, M.D., 53 Cotswold Close, Glastonbury, CT 06033, telephone (860) 633-5698.

PATHOLOGY

Available immediately. Licensed in Connecticut, Pennsylvania, New York, Alabama, and New Mexico. Passed National Boards. American Board certified. M.D. at University of Bologna, School of Medicine, Bologna, Italy. Internship at Long Island College Hospital, Brooklyn, New York. Residencies at Maimonides Medical Center, Brooklyn, New York (anatomical pathology); Mount Vernon Hospital, Mount Vernon, New York; and Yale New Haven Hospital, New Haven (clinical pathology). Seeking to join an associates or institutional practice. Please respond to: Marie Di Pasquale, M.D., 29 Old Hill Farms Rd., Westport, CT 06880, telephone (203) 226-1719.

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Connecticut Medicine

The Journal of the Connecticut State Medical Society

VOLUME 62 DECEMBER 1998 NUMBER 12

scientific:

Stephen Fleck 707 **Impediments in Treatment of Schizophrenic Patients**
Albert J. Solnit and Whitney W. Jacobs 715 **Learning from Mental Illness, Past and Present**

specials:

Richard L. Reece 721 **A Special Report on the National Congress on the Future of Medical Practice and Practice Management**

commentaries:

Wesley M. Vietzke 731 **Further Thoughts on a Sustainable Medicine**

departments:

Fifty Years Ago
735 **Dr. Senn New Head of Yale Child Clinic**
735 **Dr. Gesell Heads Child Vision Research Project**
736 **Drs. Fulton and Winternitz Receive Awards**
736 **Dr. Blumer Honored**
The President's Page
Craig W. Czarsty 737 **Report to the Semi-Annual Meeting of the CSMS House of Delegates**
Reflections on Medicine
Robert U. Massey 739 **Suicide Is a Private Affair**
Medical News Capsules
Timothy B. Norbeck 740 **This Month's Reading in Review**
Letters to the Editor
Gregory S. Slater 741 **In Response to "The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America"**
Stephen R. Katz 741 **Dr. Katz Responds**
Edward J. Volpintesta 742 **Need for Solidarity**
Samuel Spencer 743 **In Response to Dr. Katz's Commentaries**
From the Executive Director's Office
CSMS 745 **Council Meeting**
CSMS 749 **Semi-Annual Meeting of the House of Delegates**
Timothy B. Norbeck 753 **Address of the Executive Director**

general:

756 **Book Review**
758 **In Memoriam**
752 **Committee Service Questionnaire**
759 **CSMS Physician Placement Service**
761 **Title Index**
766 **Author Index**

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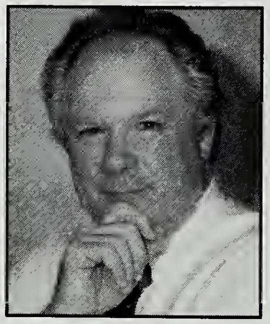

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Impediments in the Treatment of Schizophrenic Patients

STEPHEN FLECK, M.D.

ABSTRACT—Treatment for schizophrenic patients used to entail long hospitalization, including individual psychotherapy and sociotherapy, and ideally involved significant others, culminating in rehabilitation or continuation of education and follow-up treatment. Under such regimens available mostly in the private sector, one third of patients became well and another third recovered sufficiently to function in the community. There has always been a cohort of between 25% and 33% who failed to recover and who usually became chronic patients in governmental facilities. Comprehensive in-patient programs have virtually disappeared in the United States. This paper will present factors involved in this change and the ensuing deficiencies in care. These impediments will be considered under eight subheadings (see Table 1).

Introduction

SINCE Kraepelin's[1] day and the turn of the century when infections were thought (and hoped) to account for most diseases of then unknown etiology, the idea that schizophrenia had some organic cause has survived, although in mid-century, psychosocial concepts and treatments dominated—if and when treatment was provided at all. With the fortuitous arrival of antipsychotic medications in the 1950s intensive research was aimed at understanding their mode of action and quickly focused on synapses, the action sites of various beneficial psychoactive drugs and in particular on dopamine transmitters.[3] In addition new methods of brain imaging permitted in vivo studies of neuronal activity in various conditions and in response to certain stimulants.[4] Most but not all these studies resulted in some abnormal findings in some schizophrenic patients, such as increased ventricular volume, decrease of the left hypothalamus, or reduced responsitivity in frontal and prefrontal regions, to name but a few.[5] All these advances in neurophysiology and neurochemistry are important in understanding brain mechanisms and development, and appreciating the continued plasticity of the brain throughout life.[6,7] But as Hafner, a pioneer in social and community psychiatry, noted in 1987: "Our knowledge of the etiology of the disease called schizophrenia has not made much progress from Kraepelin's day."[8(p.366)] Yet advances have been made in neurophysiology and neuro- and psychopharmacology, reinforcing the belief that schizophrenia is an organic disease—"a brain disease." The well-documented efficacy of psychoactive drugs has also abetted treatment constriction, an impediment to holistic therapy which will be considered along with seven others involved in treatment limitations (see Table 1).

Faulty or Inadequate Disease Models

Advances in understanding neural integration as well as sophisticated genetic studies in recent decades have failed so far to provide us with a reliable and consistent marker for schizophrenia let alone consistent structural or functional abnormalities with the possible exception of dopamine changes in schizophrenics.[9] Yet, neurochemical and psychopharmaceutical discoveries have influenced most

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Table 1
1. Faulty or inadequate disease models restricted to the organic component(s) of the illness.
2. Introduction of antipsychotic medication as THE treatment.
3. Early discharge and transfer into inadequate therapeutic or noxious environments.
4. Possible brain damage from high doses of antipsychotic medication.
5. Injudicious psychoeducation, emphasizing chronicity intended to promote medication compliance.
6. Shortage of community services and outreach staff.
7. Prejudice—public (NIMBY)—and by insurers who fail to reimburse equitably for mental illness and employ discriminating "caps."
8. Failure to individualize treatment and involve significant others.

treatment programs, often limiting them to the giving of medication aimed at correcting or changing transmitter systems and at symptom reduction.[2] Consequently, with the vast politically and economically engendered deinstitutionalization of patients,[10] the issue of patient medication compliance has become a critical concern since it has been clearly demonstrated that relapse is positively related to medication noncompliance. Thus the pursuit of research in the "decade of the brain" has been productive, but has also abetted limited treatment focus—neuroreductionism as Uttal labeled it.[11]

Related to the emphasis on neuroscientific research has been the latter-day development of DSM classifications which define symptom clusters, an advantage over earlier more etiologically oriented diagnostic terms.[12,13] Such a more precise classification was essential for neurobiological research as well as for cross-cultural comparisons,[14] but has rendered clinical assessment topical and descriptive, as exploration and evaluation of the individual's development and personality are often slighted.[15] We have reliability at the expense of validity.[16] The wish for a single gene of etiologic significance is also alive.[17]

Antipsychotic Medication

Few if any patients arrive in a psychiatric ward who have not been medicated during the admission process. In day-hospital programs and other community-based therapeutic services, the first group formed is usually a "medication group," and other groups focus on activities or recreational projects; psychotherapy groups have become rarities. Primary concern is with patients' medication compliance. It is often considered *the* treatment. If a patient is involved in psychotherapy, usually once a week or less, it may be at an outpatient clinic separate from day-care or other programs. Overall emphasis on biological factors has skewed and limited outpatient treatments.[18,19] Although every patient is usually assigned to a case manager who coordinates the different services needed, that manager is usually not the therapist and patients have to deal with different agents or even agencies for their respective social and therapeutic needs.[20]

Early Discharge and Inadequate Resources

Community-based programs are essential for the overall policy of keeping patients in full-time hospital programs as briefly as possible, and the criteria for discharge include neither significant therapeutic involvement nor change in personal and interpersonal functioning. The focus is not on the patient's inner difficulties but on reduction of symptoms which make it possible for the patient to tolerate others, and be tolerated by others. As indicated, the change from full-time care may then be to some partial-care program or outpatient department, often with deficient or truncated service patterns which leave patients relatively symptom-free, but without meaningful experiences or goals.[10,21] There is good evidence, of course, that patients who reduce or discontinue their medication necessitate rehospitalization significantly more often when compared with patients who take their antipsychotic medication regularly. But investigating the reasons for noncompliance and careful exploration of the patient's condition and circumstances is time-consuming involving skills that may be beyond a case worker's ken. Also adverse medication effects need to be addressed.[22,23]

In addition, in many communities housing for discharged mental patients is difficult to find and often inadequate. This has contributed to the homeless population, although there are patients and others who prefer homelessness to living in uncomfortable quarters and dangerous surroundings.[24,25]

Antipsychotic Medication and Toxicity

Many side-effects of the psychoactive drugs although annoying are transitory and of little consequence, but some can be lasting and devastating. Among the latter the most important and often unalterable complication is tardive dyskinesia (TD), consisting of involuntary, jerky movements, especially of lips and tongue, and may include involuntary grimacing, conditions that render patients doubly impaired since the TD may interfere with socialization and productive occupation. The condition arises usually only after one or more years of continuous antipsychotic therapy, and its development is also dose, age, and gender-related. Medication discontinuation is indicated, as well as switching to another antipsychotic medication. But often TD symptoms persist or recur suggesting that some irreversible neuropathological change has occurred, although some schizophrenic patients develop tremors without ever having been on medication.[26,27] Among less severe side-effects are Parkinsonian tremors, akisthesia, and others, usually controllable with anticholinergic drugs. But all psychoactive drugs, including minor tranquilizers, change neuronal and interneuronal activity, possibly damaging cells.[28] However, the risk-benefit balance usually favors medication if carefully monitored.

TD incidence rises with age and is more common in women, but after one year or more of continuous antipsychotic medication the incidence may already be 20% or more and after 25 years two-thirds of patients suffer from it.[29] It is a condition that must be explained to patients before they may agree to be medicated. But the ethical problem of "informed consent" from psychotic patients is difficult as patients may have difficulty understanding consequences. Lasting changes in neurotransmittors may be involved in symptoms changing from positive to negative.* Therefore, such risks must be considered and weighed against the established effectiveness of psychoactive drugs. The newer antipsychotics, such as olanzapine or risperidone change the risk-benefit balance favorably. However, because they are expensive their use in many settings is restricted and new patients are still often started with the older, cheaper medications.

Psychoeducation

Psychoeducation has become an important element in treatments aimed at informing patients themselves about their condition and the necessity for prolonged treatment, and for educating significant others about the patient's problems and needs as well as tending to their own concerns.[30] Psychoeducation, including family treatment, is very much in order to change possible noxious influences deriving from significant others such as high emotional expression.[31] But here too the beneficial is mixed with adverse elements in that in many such programs the chronicity of schizophrenia is emphasized, often likened to diabetes, requiring life-long need for medication.[32] Such iatrogenically induced dependency on medication may of course be unrealistic as many psychiatric patients improve and recover without medication continued indefinitely,[33] and some schizophrenic patients recovered before psychopharmaceuticals arrived.[34,35,36] But the opportunity provided by psychoeducational programs to reduce noxious interactions and traumatic behavior affecting the patient is valuable.[37,38] The importance of early and continued involvement of significant others will be discussed later.

Resource Shortages

Programs not limited by the conviction that schizophrenia is an "organic" illness, can provide comprehensive care with or without medication.[39] They need experienced staff including individual and group psychotherapists, and other specialists providing psychosocial rehabilitation or habilitation, and educational opportunities, as well as outreach staff for those patients who cannot or will not come to an agency and who need to be supplied with medication as well as efforts to motivate them to participate in the community. In most constituencies, there are staff shortages for implementation of such assertive community care programs that were first advocated by Stein and Test who also demonstrated their effectiveness[40,41,42]. However, effectiveness is often measured by the need for rehospitalization, and unfortunately preventing this is often the goal of community outreach programs, usually because there is insufficient staff for other forms of group work, for education and rehabilitation, or psychotherapeutic programs.[10,43,44]

Discrimination

Prejudice against the mentally ill remains a serious hindrance, and rarely is the establishment of a group home or similar agency possible without considerable opposition from the neighboring inhabitants—NIMBY, "Not in My Backyard." Furthermore discrimination against the mentally ill in employment persists.[45] Another form of discrimination-driven impediment to treatment in the United States consists of discriminatory insurance practices. Whereas managed-care infringements affect all of medicine, they may well be more common or severe for mental illness. Often the response of a managed-care agent to a required weekly report is "well it has been two weeks, and the patient has not responded. There should be some other treatment," or if the patient has responded, the message may be that the patient no longer should be in full-time treatment. Such instances are not unusual in my experience.[46] In general, disadvantageous provisions for mental illness remain and these are particularly severe in the private-care-oriented United States. But there are also similar interferences or treatment limitation under government-sponsored care.[47,48] Utilization review is not limited to the private sector.

An administrative form of discrimination exists regarding the so-called dual diagnosis patient. In many states patients with mental illness and patients with substance abuse problems are the responsibility of separate authorities. The mental health department shifts patients to sub-

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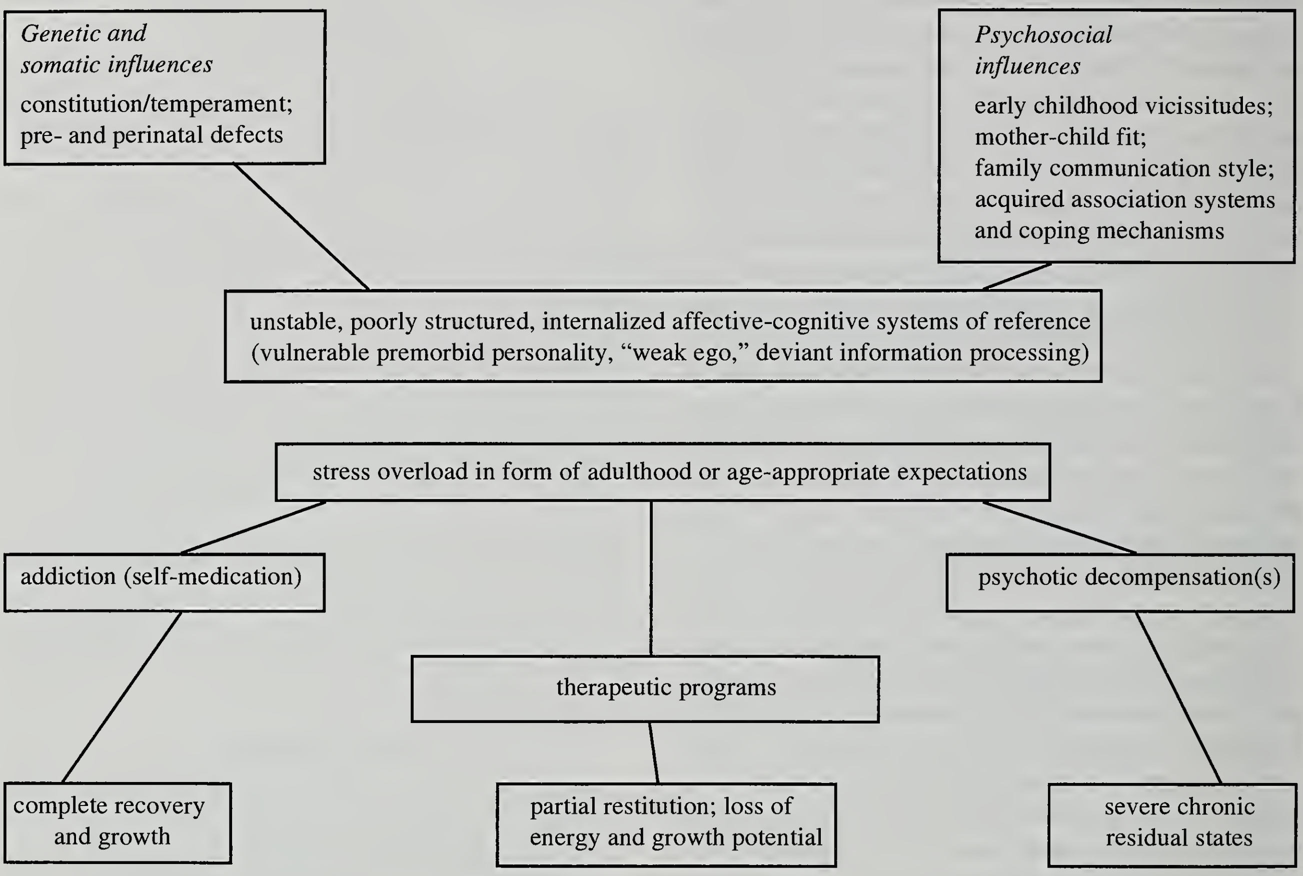
*Positive symptoms are those of agitation, aggressiveness, active hallucination or delusions; negative symptoms include apathy, passivity, withdrawal, etc..

Figure 1.—Model for Development and Course of Schizophrenia


Genetic and somatic influences
constitution/temperament; pre- and perinatal defects
Psychosocial influences
early childhood vicissitudes; mother-child fit; family communication style; acquired association systems and coping mechanisms
unstable, poorly structured, internalized affective-cognitive systems of reference (vulnerable premorbid personality, "weak ego," deviant information processing)
stress overload in form of adulthood or age-appropriate expectations
addiction (self-medication)
psychotic decompensation(s)
therapeutic programs
complete recovery and growth
partial restitution; loss of energy and growth potential
severe chronic residual states

stance-abuse programs which in turn refuse treatment to patients with psychiatric diagnoses, especially patients on psychoactive medication. Both authorities have cogent administrative reasons for their policy but many severe addicts are mentally ill to begin with, and other addicts eventually become mentally ill. If a diabetic patient breaks his leg, we don't speak of "dual diagnoses," let alone go to different insurance programs or authorities for his two disorders.[49]

Failure to Individualize Treatments

Finally, a most important problem is the failure to individualize treatment. A patient coming to an agency is often fitted into a program instead of a program being fitted to him or her. It is one of the difficulties besetting work with schizophrenic patients that each patient is an individual and although two patients may have identical symptoms, their illnesses and personal and developmental histories are not identical, not even for identical twins, yet they may very well be treated with identical measures. As I shall detail further, no impediment to adequate treatment is greater than our failure to individualize treatment and to involve significant others from the beginning of professional contact or as soon thereafter as possible.[33] There is ample evidence and documentation of patients recovering with prolonged psychotherapy in hospitals and beyond prior to the availability of psychoactive drugs.[34,-36,51-54]

As Table 1 shows, there are many hindrances to integrated care and treatment of schizophrenic patients. To begin with, any approach that covers only one segment of the biopsychosocial intersystem ambiance in which we all live is partial and insufficient.[54,55] It may be possible to cure a patient of appendicitis without ever knowing her or even much of her medical history. But, when it comes to surgical or other after-care, the patient may need guidance as well as support and nurturing. As physicians have observed over the centuries, when it comes to treatment it is more important to know what kind of patient has the disease than what kind of disease the patient has.[56]

Unfortunately, schizophrenic patients—or other patients—are not "one kind of patient." Although we have succeeded in the last 15 years to classify schizophrenic manifestations in an orderly and consistent manner,[57] and these diagnostic classifications are topical and reliable, but they tell us little or nothing about what kind of person has the disease, nor about his relationships and background. DSM IV does not address relationships or personality (other than formal "Personality Disorder" (Axis II)) nor is it sensitive to cultural differences.[58,59]

Clinical manifestations must be explored in terms of their development, which may be rooted in some organic or inborn defect or deficiency, but also may involve noxious psychosocial influences or trauma to achieve phenotypical expression. This double-whammy phenomenon has been demonstrated by many investigators, most notably by Tienari and colleagues in Finland.[60,61] Our developmental complexities must be appreciated; this is reflected in the diagram modified from Ciompi, et al[62] (Fig. 1). These multiple paths to diagnosable illness demand that evaluation of the patient's condition also be multifaceted, and that treatment plans attend to this complexity. If possible, an assessment needs to be made of longitudinal deviations from wholesome development as well as of the familial or equivalent context regarding possible wholesome and compensatory interactions or pathology-reinforcing behaviors.[62-65] It must be appreciated, however, that any system interaction is a two-way or multifaceted process and that any notion of linear causation is out of place in our field.[66-69] (See Table 2.)

An adequate and comprehensive model of schizophrenia would include possible genetic, intrauterine, and postnatal etiological factors, none of which of themselves constitute sufficient cause for the phenotypical expression of the disease. This has been most cogently demonstrated by the Finnish adoption study demonstrating the roles of both genetic vulnerability and environmental pathogenic effect.[70] Such a view fits the data we have up to now suggesting that there are neuropathological events related to embryonic stages of neural tube development, probably in the second trimester, as well as evidence of family pathology. This was amply documented earlier in this century especially with regard to communication deviancy in the family.[71,72] The brain is not a static mass of interacting cells at any life stage; although encased in sometimes very thick skulls it is in systemic interaction with the rest of the body as well as the outside world.[73,74] Likewise, family interaction is never static and may change in accordance with life-cycle stages (or fail to change when it should) as well as through interaction with the surrounding community and culture.[75]

Treatment Examples

Figure 1 illustrates a comprehensive model for the development of schizophrenia indicating also the need for comprehensive treatment. In terms of current knowledge, an adequate model of the disease (or diseases) must take into account the total hierarchy of systems involved with human existence. It is crucial to consider complex phenomena like schizophrenia in systems terms, ie, all elements in any system are interactive and not reactive in linear fashion. Besides, systems contain subsystems and interact with other systems, eg, the individual, his or her family, the community, etc.[76]

Table 2.—Hierarchy of Systems
Chromosomes/genes
Cells
Organs
Organ systems
Individual-organism
Family
Community
State or nation
World organizations
Universe

Encompassing models call for comprehensive treatment choices responsive to system—defects or malfunctioning, as they can be assessed only in clinical work by thorough investigation of the biological, the psychological, and social elements presented by the patient and the family. Alanen and coworkers in Finland have demonstrated the effectiveness of such "need-adapted treatment."[33] Their treatment programs are devised for each patient based on initial pre-admission clinical assessment by a team involving, ideally, both patient and significant others.

Langsley et al demonstrated long ago that such a program often obviates the need for full-time hospitalization.[77] The "need adapted treatment assessment" may or may not go beyond one session but whenever completed, a treatment plan, usually a combination of treatments, is proposed, geared to the particular needs of the patient and the significant others. They include chemotherapy, individual psychotherapy, family therapy, group therapy, and rehabilitation. These treatments may be employed singly or in various combinations as the need assessment indicates. There is also flexibility, as different needs or indications arise, and the patient may switch from one form of therapy to another or add a second or discontinue one but continue with another. One of the team members becomes the patient's therapist following him or her regardless of the patient's residence.

Treatment is not predetermined by a conviction of a particular etiology, nor by limitation to one particular program, which is so often the case in our clinics and community services. Need-adapted treatment in the community encompasses what used to be done or accomplished in well-staffed and psychotherapeutically oriented inpatient services and after-care, usually individual psychotherapy. Whereas such programs were available only to the affluent or well-insured, with the arrival of community psychiatry we should provide such programs in the community for all patients so that we can achieve recovery and rehabilitation with at least a significant majority of schizophrenic patients.[78–81] In such programs, most impediments outlined earlier may be avoided or ameliorated.

Experience in Finland as well as in the third world,[82] has also shown that the need for medication is much lower than in treatment programs for schizophrenic patients in the industrialized world, and that some 60% of the patients achieve satisfactory levels of functioning with about 30% being free of signs and symptoms after two years or more. There must also be flexibility in frequency of appointments, unlike in most of our community services where a patient's schedule is usually determined by the clinic's or clinicians' needs instead of the patient's. Another project which has been around for many years called Soteria, houses patients in a "normal" environment where each is paired with a caretaker who works with him therapeutically for an indefinite period of time. Most of these patients recover often without medications although at a slower pace than in hospital services, but their relapse rates are lower than for hospital-discharged patients.[83] The need to adapt programs to the condition of the patient cannot be overemphasized. Stereotypical programs and limited models of disease impede care and treatment.[84]

Economics

I have not touched upon a major overarching impediment: MONEY. Of course, everybody wants cost-effectiveness—the biggest bang for the smallest number of bucks. Although mental illnesses are among the most common disabling disorders—maybe the most common, and despite great research expenditures in the Decade of the Brain, they amount to less than 10% of the total of medical research funds—public and private.[85] But money for treatment is what matters most.

It is hard to be rational about an irrational situation, ie, that health care, a basic human right be provided for profit.[86] True, many of our essential services are rendered for profit, but that doesn't mean it is always rational. We don't expect the Army or Navy to operate in such a way that Admirals and Generals can draw seven figure salaries plus bonuses. Our taxes pay for these services, because we must share this expense. The same principal should apply: since I can't afford to buy my own tank or B52, I help pay for it through taxes, and this should be just as true of medical care, eg, up to $70,000 a year for one patient's medications!

Besides the inequity of leaving millions of Americans without any insurance, there is additional discrimination toward the mentally ill. Although they have been the responsibility of public agencies for the last 150 years or so, this has been no boon for most patients. It not only resulted in what Deutsch in 1948 called the shame of the states—overcrowded, understaffed snake pits called hospitals,[87] but also helped motivate our governors around that time to deinstitutionalize patients before the availability of psychoactive drugs. With the help of medication, deinstitutionalization mushroomed without providing commensurate community care resources.[10]

Inadequate public services, interference with care from "managed care" whether public or private has been reported for over half of patients in need of full-time care; no accurate figures are available as to curtailment of outpatient care. Many insurance programs limit the number and frequency of psychotherapy sessions.[88] It must be recognized however that there also has been exploitation of generous insurance provisions in the past especially by for-profit psychiatric hospitals. Such abuses can be spotted and corrected more easily than changing the over-all policy and the belief that profit and competition will stabilize the "health-care market," as if it were a matter of exchanging or selling goods.[89–91]

Whereas our knowledge and treatment methods are far from ideal, there are effective therapies for most mental illnesses which should be available for all patients unimpeded by insurance priorities or prejudices of any kind—not scientific or public, not political or economic.

As for for-profit managed health care, we must undo the insanity of treating health care as an industry or business. Health care is service, whether by individual professionals or professional groups and, like any service, it needs to be paid for. This should be accomplished in the simplest and least bureaucratic fashion. Such a system, as it operates in Canada, would save 50% or more of "administrative overhead," and we'd be ahead by having everybody covered when sick. Then impediments to treatment can be limited by our actual skills and knowledge, not by preconceived illness models, nor by profit economics. It is our responsibility as physicians along with other health-care professionals to move toward a sane, economic, and fair system of providing care. This is a political task and as citizens with special skills and the unique task of tending to our fellow-citizens who are sick and handicapped we must deliver on this calling by insisting that health care is for everyone regardless of income or the nature of the disability.

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Learning from Mental Illness, Past and Present

ALBERT J. SOLNIT, M.D. AND WHITNEY W. JACOBS

MODERN understanding of mental illness was set in motion by Freud. His effect on the field took years to grow, becoming broadly evident just as the 19th became the 20th century, roughly a decade before a new book began Connecticut's own, almost unique chapter in psychiatric history.

This was the 1908 publication of *A Mind That Found Itself*, by Clifford W. Beers of New Haven. His graphic, autobiographical tale of years of struggle with manic depression psychosis was frequently reprinted for more than half a century. Early grievous difficulties that he mentioned still retain a familiar, lingering echo.

Yet it is important to recall that Beers authored what might be considered the first popular book written by someone with serious mental illness. Further, Beers' dedication, enthusiasm, and work led to the founding of the Mental Health Association of Connecticut, observing its 90th anniversary this year. He and associates also spawned the American Foundation for Mental Hygiene, which became the National Mental Health Associaiton (NMHA), and in turn helped form the World Foundation for Mental Health.

The development of respect for the value of opinions, insights, and potential talents of people with mental disabilities, their families, and other lay advocates can steadily be discerned in Connecticut. This grew as significant clinical and scientific advances were made, encouraged by related and supporting organizations like NMHA itself and, more recently, the National Alliance for the Mentally Ill and its branches in Connecticut and all other states in the nation.

All Learn Together

As a psychiatrist-teacher and researcher, and as a writer, for several decades it has been clear to us that teacher and student frequently enlighten one another. This is obvious if one analyzes their mutual relationship. Most teachers learn at times from eager, searching young people.

One of the most penetrating lessons came during the last seven years to the Commissioner of the Department of Mental Health and Addiction Services (DMHAS) from a new and different body of "students." Some were among the more than 30,000 patients, hospitalized or not, many young adults, annually receiving treatment for mental disability through DMHAS' staff, facilities, and funded programs.[1]

It might sound contradictory to suggest that one can learn from those with mental illness. But in a real sense, quietly, subtly, and gradually, all of us, professionals and laypersons alike, have long been learning from them, especially during the most recent 15 years or so.

This is happening, too, among people with substance abuse disorders, since 1995 an added DMHAS responsibility. Yet this report emphasizes conditions in the mental health field. Changes in the substance abuse area may differ or evolve separately and should be discussed in a separate paper.

At the beginning of the last 15 years, more than three quarters of the department's money and effort were spent on its mental hospitals. *DMHAS' inpatient census hovered about four times higher than at present.* Few people then held expectations of recovery for mental patients.

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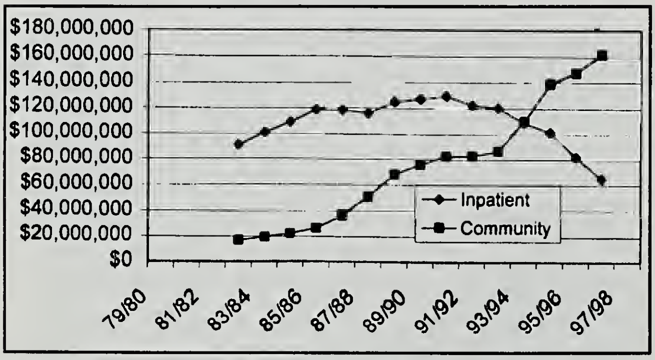
Studies in Connecticut itself and other places indicate that many people with mental disabilities in publically supported hospitals have significant physical problems as well, often treated medically in those same institutions. The change from hospital to community living during this time for many of these people meant care for physical difficulties, as well as for mental illness, would more often be provided by community physicians, dentists, and other health professionals in private practice or community clinics.[2]

Many advances brought new knowledge to bear on the mental illness problem. Equally important, broadening new opportunities for work and education for people recovering from mental illness gave them significant new opportunies and insights about being in charge of themselves, adding importantly to their motivation and self-esteem.

As these individuals demonstrate and increase their sense of self worth, society, too, slowly gains recognition and understanding of this, seeing more promise in them, helping to erode false myths, and the destructive stigma that often surrounds this population.



Reversal in proportions of DMH-DMHAS budgets for "Inpatient" and "Community" mental health program expenditures since FY 1983. Amounts shown approximate actual dollars but are rounded emphasizing trend alone, and may include some substance abuse funding until FY 1989 because of accounting methods. Not intended for detailed analysis. (From DMHAS.)

Effects of changes brought about by burgeoning clinical, biological, and rehabilitation knowledge, much of which strengthened possibilities for mental patients to live in the community, have slowly been felt across the state since 1983. In spring of that year a blunt, critical report from the Connecticut "Governor's Blue Ribbon Task Force on Mental Health Policy" touched off continuing gradual improvment in DMHAS owned or funded "community" treatment programs and facilities.

Connecticut was particularly fortunate at that time, as physicians may best appreciate. It had two medical schools with broad research interests in mental illness and related topics. Further, each school also has its own federally-supported research center studying disorders that may complicate mental illness: drug abuse at Yale in New Haven and alcoholism at the University of Connecticut School of Medicine in Farmington.

New knowledge revealed by related research at both universities often improved treatment. Since DMHAS is now also responsible for care for both mentally ill people and those facing substance abuse problems, this point is relevant to both these populations. Further, studies in many locations indicate that roughly half of each of these two populations have the "dual diagnosis" of co-existing psychiatric and substance abuse disorders.

Along a complementary path, DMHAS has for more than a decade conducted mental illness research often focused on learning whether people with mental illness could both live in the community and successfully receive locally essential treatment and rehabilitation services needed to enable them to maintain personal stability while promoting recovery.

Studies Aid Changes

For instance, in the late 1980s DMHAS began evaluating the contributions local "crisis centers" might make. Could such centers, and their crisis intervention teams significantly reduce emotional (and financial) costs and need for hospitalization, and the resultant disruption of their lives for "community" residents struggling with mental illness?

Both answers were decidely affirmative. Connecticut now has 11 such centers. Through them prompt crisis assessment and appropriate short-term treatment are available near where most people with mental illness live in communities. Later, in the 1990s, existence of the centers—part of continuing development of DMHAS-funded community facilities and programs—was a major reason DMHAS felt that two of its three major mental hospitals could safely first be downsized, then closed: Fairfield in December 1995 and Norwich in October 1996. The state's legislature and administration also studied and authorized these closures.

Having such centers, too, was cited as an important factor when Connecticut tied in 1990 with Ohio as having the fourth best public mental health agency in an independent country-wide rating by the National Alliance for the Mentally Ill and the Public Citizen Health Research Group.

In another example a medication (clozapine), now used primarily to combat long-term schizophrenia, was newly introduced for general use in this country in 1990. But per-patient cost of about $8,000 a year made a study of cost-effectiveness essential. DMHAS received federal financing for a broad three-year research study of the question based on future field experience in DMHAS hospitals. An early, central finding for psychiatrists, people with mental illness, and taxpayers was that rehospitalization in the critical six-month period following discharge was about six times lower for clozapine recipients than those receiving other antipsychotics. This information strongly supported the legislature's decision in 1994 to increase appropriations for clozapine.[3]

Connecticut became one of the first states in the nation to legislate adequate financial support to make the promise real that any medically eligible state patient could receive clozapine. Many such Connecticut patients, a few after decades of hospitalization because of refractory schizophrenia, are now living in the community. Some of them who had years of hospitalization before receiving clozapine have since gone back to college or full-time jobs—even financial independence. All such recipients still have schizophrenia but are sustained in their improved lives by community services.[4]

National Developments Help

Of course Connecticut does not exist in a vacuum, nor has it single-handedly solved all its difficulties with mental illness. Nationally, rising efficacy of treatment for mental illness in recent years has been one of the most important factors underlying the Connecticut developments. In fact, in 1993 a special study, requested by the U.S. Senate Committee on Appropriations and performed by the National Advisory Mental Health Council, reported:

"Many myths and misunderstandings contribute to the stigmatization of persons with mental illness and to their often limited access to needed services."

Further, indicating how effective such services can be, the report continued:

"For example, millions of Americans and many policy makers are unaware that the efficacy of an extensive array of treatments for specific mental disorders have been systematically tested in controlled clinical trials; these studies demonstrate that mental disorders can now be diagnosed and treated as precisely and effectively as other disorders in medicine."

Stressing, yet qualifying the point, the report added, "The existence of effective treatments is only relevant to those who can obtain them."

Legal Action Strengthens Patient Rights

Earlier a 1988 federal class action lawsuit by the Connecticut Civil Liberties Union pitted this state's mental hospital patients against the (then) Department of Mental Health. Before the 1993 Senate report, results of the Connecticut suit were already strengthening the rights of patients to help themselves obtain these services.

A Consent Order ended the litigation in 1989—to which plaintiffs and DMH agreed, the latter without admitting liability. These effects occurred:

- The Connecticut Legal Rights Project (CLRP) came to life in 1990 to assure and foster plaintiffs' rights. DMH gave willing cooperation. CLRP first set up branches to represent patients in the three main DMH hospitals, Norwich, Connecticut Valley (Middletown), and Fairfield Hills (Newtown).
- CLRP, working with DMH, also developed a statewide grievance procedure for DMH patients. Under it, for example, such a person must agree before his or her treatment program can proceed.
- CLRP's newest effort, in August 1994, began a teaching program to educate people recovered from mental illness aiming to become professional advocates for people with the same disorder. The former Community Advocacy Education Division, now Advocacy Unlimited Inc., directed by Yvette Sangster, operates a 14-week curriculum illuminating complexities of the mental health system. Some 75 graduates—only recoverees from mental illness are admitted—have completed the course. Teachers include guest legislators, DMHAS officials, business leaders, attorneys, and others with vital information related to the mental health system and its operations.

Another New Education Plan Begins

A different educational venture began in 1992. Sponsored by DMH and nationally unique to Connecticut, the two-semester community college program, leading to a certificate, teaches persons recovered from mental illness and other students preparing to be workers in the mental health system itself. Half of each class are people who have recovered from mental illness.

Jessica Wolf, Ph.D., then a DMH official, started the program at Housatonic Community-Technical College (HCTC) in Bridgeport. It broadens prospects for persons recovered from mental illness for education and employment, recognizing their latent talents and relevant personal experiences in the mental health system. Many graduates are now full-time staff members within DMHAS or its funded programs.

The two-semester MERGE (merging mental illness and education) plan was so successful at HCTC it was emulated two years ago at the community college in nearby Norwalk and this year by the community college in Hartford. Dr. Wolf secured a $106.000 federal grant, and funding from DMH and other sources, to bring the plan to life. She continues to guide its expansion. In August 1997, she retired from state service to pursue other interests.

One of 43 MERGE graduates is a person who worked first for a long period himself, later overcoming mental illness. Today he has a record of more than four years of service helping others with the disorder at a DMHAS-funded community mental health center. Recently he declared with enthusiasm, "Now I have the best job I ever had."

Recovered Patients Gain Government Posts

Another change is revealed in the Connecticut story about mental illness.

Almost a quarter century ago in 1975 this state's legislature established an advisory system for the (then) Department of Mental Health. Authorized were hundreds of volunteer representatives, a few from each of the state's 169 towns, to ask informed questions, perform evaluations of services, and provide advice on local mental health needs for DMH (now DMHAS).

State advisory system law calls for a certain proportion of such representatives to be "consumers." But the meaning many years ago did not include mental patients. Tentatively, as the 1980s began, a few people recovered from mental illness were appointed to advisory system vacancies.

Now, as the 1990s end, virtually all of Connecticut's 23 Catchment Area Councils (CACs) and all five coordinating Regional Mental Health Boards include at least one self-identified person recovered from a mental disorder. One has been appointed to the all-volunteer State Board of Mental Health and Addiction Services, which oversees the statewide advisory organization. Advisory units analyze DMHAS budgets, services, and other major departmental concerns, including our present focus on a public managed care system. (Coincidentally, the word "consumer" today has come to be used commonly as a synonym for mental patient, someone who may "consume" treatment services for that illness.)

Is "Community Living" Working?

It may take decades to learn all the significant effects of the evolution from hospital to community living for most persons with serious mental illness under DMHAS care.

Yet in an early attempt to learn some fundamentals about what the change means to those most needing "community-based mental-health services" provided by DMHAS, the department reported in September 1996 on a follow-up study called "Community Adjustment Among People with Serious Mental Illness in Connecticut." This was the largest such study done in this state and among the largest nationally.[5]

As the Executive Summary explained, the survey represented primarily the opinions of community-related "mental health staff." Of the 20,000 people under DMHAS care not hospitalized and "living in the community" at the time, more than one third, 6,850, were in the sample evaluated.

People directly interested in care for those with mental disorders will find it informative to review the whole survey. It provides broad support for the idea of community living rather than hospitalization for most of this population. In their key assessment the team found "... most clients ... clinically stable, not experiencing severe psychotic symptoms, and ... medication compliant." They also found 20% of all patients had a "medical condition that was a complicating factor in their psychiatric treatment."

The study sample included somewhat more people between 40 and 59 years of age than the general population of Connecticut. The main significance seen in this report section was that people confronted with "a variety of complex social and economic problems are able to obtain access to public mental health services."

Among "Diagnostic Characteristics" of those studied, the report said:

"Ninety-one percent ... had some form of major mental illness." Of these 59% had a schizophrenia-related diagnosis; 25% had major depression or bipolar states, and the remainder had "other" psychiatric difficulties. Co-existing substance abuse was found in 31% and personality disorders in 40% "of all study clients."

The Survey learned that 75% had avoided involvement in "any disruptive behaviors during the past year (1994–1995) and "the remainder had engaged in typically minor 'trouble making.'" Comparing the study group with Connecticut's population, the survey report said data support the view that "violence acts were *not* more likely to be committed by people with serious mental illness." (italics added.)

By contrast, the study found people with serious mental illness living in the community "were at substantial risk of becoming the victims of certain crimes." They were victimized by people committing rape, sexual assault, simple and aggravated assault, and major theft of property at "dramatically higher" rates than people in the general population, the team reported.

Connecticut's Future Role

Connecticut's citizens have made significant contributions in relation to mental illness since early in this century. At the moment promising studies and efforts are underway in this state which may lead to prevention of mental illness, or minimizing the extensive damage it can cause once it appears.

Just as Connecticut citizens played leading roles in the long, successful fight to prevent polio, so many of them are now engaged in working to prevent the ravages of mental disorders.[6]

END NOTES

1. Readers familiar with recent state organizational changes know that in 1995 DMH was given added responsibility by the Legislature for state substance abuse programs, formerly the province of CADAC, the Connecticut Alcohol and Drug Abuse Commission. DMH then became the Department of Mental Health and Addiction Services.(Some states now call such combined programs "behavioral health" activities. To minimize confusion we are not using that term here.)

   Nearly all developments discussed here took place when DMH had responsibility for mental illness only, so that disorder is the basic subject of this paper. Also, statistics in this article apply only to mental illness. Example: early on, we said more than 30,000 patients annually are cared for through DMHAS programs. That figure is for mental disabilities alone. The annual total of mental, together with substance abuse, patients cared for by DMHAS is around 60,000.

2. This appears generally true. Examples: "Medical Comorbidity in Schizophrenia." (U.S.) Review. *Schizophr Bull* [121 refs] 1996; 22:413–30, where it is noted: "Patients with comorbid conditions are usually excluded from research studies, although they probably represent the majority of individuals with schizophrenia ... [but] results suggest that schizophrenia patients may receive less than adequate health care." Also, "Dental Health Behavior and Self-reported Dental Health Problems among Hospitalized Psychiatric Patients in Denmark." *Acta Odontologica Scandinavia* (in English) February 1995; 53:35–40, Paper stated: "The study underlines the need for specific preventive dental programs, which aim at improving the poor dental health behavior among psychiatric patients." Same paper reported: "Hospital dental programs like the one found at this hospital have only been established in one-third of the psychiatric departments in the country," which has a governmental health care program.

3. "Clozapine Eligibility Among State Hospital Patients," *Schizophr Bull* 1996; 22:22, Senior author, Susan M. Essock, Ph.D., then chief of DMHAS psychological services. Honored twice for her work: April 1993, award at annual meeting of Connecticut Psychological Association; September 1997, "Julius Laffal, Ph.D." award at Connecticut Valley Hospital. Early findings from this research became available to legislators and other officials studying immediate DMHAS funding needs before 1996 paper publication. Helped minimize delay for improvements benefiting consumers in DMHAS programs. Information quoted in this article, later included in publication cited, was from a poster presented at the American College of Neuropsychopharmacology in Honolulu, HI, 13–17 December 1993.

4. At the end of July 1998, the manufacturer of the medication, Novartis Pharmaceuticals, reported that 1,401 Connecticut residents were receiving clozapine. The company said then it did not have a complete statistical analysis but "most" Connecticut recipients were " state" patients (ie, within DMHAS programs).

5. Survey team members: Wayne Dailey, Ph.D.; Kenneth Marcus, M.D.; Larry Davidson, Ph.D.; Eva Vavrousek-Jakuba, Sc.D.; Lynne Garner, Ph.D.; Jack K. Tebes, Ph.D.; Susan M. Essock, Ph.D.

6. This article dealt with major changes in recent years from hospital-based care for mental illness by DMHAS to the "community" emphasis in effect today. Significant subsidiary problems remain and are being faced by the department, some beyond the scope or its authority and/or power to change.

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A Special Report on the National Congress on the Future of Medical Practice and Practice Management

RICHARD L. REECE, M.D.

I recently attended the "National Congress on the Future of Medical Practice and Practice Management" in Nashville. The word "Congress" fits this event. Four hundred people came. They represented most major physician organizations. This Congress, unlike the U.S. Congress, had no power to create or pass laws. But like the U.S. Congress, the air was filled with political opinions, anecdotal stories, and tales of treachery and disillusionment. Physician leaders represented these physician organizations:

- Integrated Medical Groups
- Independent Practice Associations
- Group/IPA Hybrids
- Tax-Exempt Clinics
- Physician Practice Management Companies
- Hospital Based Groups
- HMO Staff Models
- Physician-Owned Health Plans
- Physician Unions
- Academic Medical Centers
- American Medical Association

The Congress—Quite an Affair

This "Congress" was quite an affair. Before I interpret what went on here, let me quote from the press release promoting the program:

At the National Congress on the Future of Medical Practice and Practice Management scheduled for Thursday, 22 October though Saturday, 24 October 1998 at the Opryland Hotel in Nashville, Tennessee, senior physicians and financial leaders will discuss the serious decline of the physician practice management industry and alternatives for restructuring the management of physician organizations. Numerous prominent physicians organizations, including the Mayo Clinic, the Cleveland Clinic, the Ochsner Clinic, the Marshfield Clinic, PhyCor, MedPartners, Coastal Physician Group, MedCath, and Harvard Vanguard Associates, will make case study presentations regarding their organizations and culture and the challenges they face in the future.

Senior investment analysts including Daniel Cain of Cain Brothers & Company, Benjamin Lorello of Saloman Smith Barney, James Hoover of Dauphin Capital Partners, Douglas Townsend, Jr., of Townsend, Frew & Co., Douglas Sherlock of the Sherlock Company, Robert Daly of MedEquity Investors and Bernard Ferrari, M.D. director of the worldwide health care practice of McKinley & Co, will discuss the future of the practice management enterprise.

The National Congress on the Future of Medical Practice and Practice Management features over 90 experts on physician organizations and practice management addressing a variety of topics form PPMCs and tax-exempt clinics through physician-owned health plans and physician unions.

What did all the aforementioned physician organization leaders and senior investment analysts share in common? They believe physicians loyal their own organizations are at the very core of any successful, cost-efficient, outcomes-effective, and consumer-pleasing and patient-satisfying health system.

RICHARD L. REECE, M.D., pathologist,Hartford Hospital, editor-in-chief, *Physician Practice Options*, a national monthly newsletter, and resides in Old Saybrook.

The Mood of Physicians as They Left the Congress

I made it my business to talk to as many physicians as I could about why they came to this Congress and what they learned. I got a variety of responses—some negative and some positive. As nearly as I could tell, about 50 physicians came. It's hard to tell because, in the new spirit of egalitarianism, organizers decided "MD" shouldn't appear on badges or on the attendance list. More than one physician to whom I spoke complained. Said one: "I went to medical school, not provider school." Another commented: "Is this a conference about what physicians think the future is, or is it a conference for lawyers, analysts, accountants, and investment bankers?"

The Burning Questions

The burning questions in Nashville, as well at on Wall Street and Main Street, were: "How do you organize doctors for profit?" "How do you put them together in organizations for the good of patients, for their own good, for the good of their communities, for the good of the nation, and, of course, for the good of investors?" "Are these various goods, which are often clashing, compatible with a rational and compassionate health system? The biggest question of all was: "Why hasn't anybody been able to come up with an organizational model that satisfies and motivates most mainstream medical practitioners?"

The answer is fairly obvious. The U.S. is a vast continental nation with a heterogeneous population served by a diverse group of physicians—two-thirds specialists, one-third primary care, one-third in solo practice, over half in groups of three or less, and nearly one-half on salaries. Three-fourths practice in metropolitan areas or suburbs dominated by managed care and serving corporate payers; the other quarter are in rural America with its disproportionate number of Medicaid and Medicare recipients. These numbers simply don't add up to a one-stop solution.

Anti-managed Care and Anti-ownership Attitudes

Most practicing physicians have rejected HMOs (a recent poll has indicated 70% of doctors are anti-managed care); they've rejected hospital ownership (after practices are acquired, their productivity drops 20% to 40%, and the hospitals lose somewhere between $50,000 to $125,000 per physician per year), and they've rejected Physician Practice Management Companies (whose stock value has dropped about 70% this year.). In a larger and different sense, physicians have rejected the major business principles, viz., that the path to survival and efficiency lies solely in integration into large systems or consolidation into large groups.

The Mood of the Congress

John Cochrane, editor of *Integrated Healthcare Report*, captured the Congress best when he asked these questions in his talk on "The Future of Integrated Healthcare Systems."

- Is managed care dead?
- Can anybody manage an IDS, an HMO, a PSO, or a physician practice?
- Will the real IDS stand up?
- Is it the strategy or the execution?
- What are you missing if you don't pursue integration?

He then went on to say managed care had actually peaked or leveled off in certain markets, and offered this table to clench his point.

Level or Declining HMO Markets

Metropolitan Area	7/96, % of population	1/97, % of population
Phoenix	33%	33%
Des Moines	26%	26%
Boise	5%	7%
Seattle	21%	23%
Milwaukee	43%	29%
Chicago	22%	22%
Cleveland	20%	23%
Memphis	24%	23%
Nashville	23%	21%

Can this managed care stall-out *possibly be?* Can the relentless much-heralded march to mature managed-care markets *be over?* Can it be that Integrated Delivery Systems *will not dominate* the landscape, that 85 to 95% of insured people *will not be in HMOs or PPOs,* that *hospital use has bottomed out,* that consumers *will reject rather than embrace managed care?* Is is possible that most *physicians will not be in large groups?* Are thoughts of "integrated health-care," markets driven by quality rather than price, creating a unified culture, defining "value" in terms acceptable to payers and consumers, and developing physician leaders who agreed with physician executives, *just a pipe dream?*

Frustration

I could sense Cochrane's frustrations. He was trained as a hospital administrator and has extensive experience as a senior executive in integrated and mature California health care systems. Don't physicians realize, he seemed to ask, that the future surely lies in integrated systems? But instead of integration, he lamented, we have dis-integration. The reality, said Cochrane, is that we have shakeout.

- HMOs are bleeding red ink.
- Purchasers, consumers, and government are clamoring for greater accountability, and more choice—all of which increase premiums.
- HMOs are selling physician practices.
- HMOs are abandoning Medicare & Medicaid markets.
- Physicians are quitting HMO panels and joining unions.
- Physician Practice Management companies are on the ropes.
- Health systems are shedding money-losing HMOs and physician practices.
- Integrated Systems seem to be falling apart and are responding to newsbytes, rather than going forward with rational planning.

Failure of Physicians to "Play Ball"

What was the underlying message in Cochrane's excellent talk? Physicians are a cantankerous lot who don't want to seem to play ball with executives and other professionals in large organizations. The only want to play ball with their fellow physicians. Physicians form their own cartels to protect their specialties and their incomes. They're hard to "integrate." They're apathetic to organizational leadership, and lack resolve to carry through on organizational goals. It's very difficult to get them to "align incentives" with a large organizations, and for organizations to win their trust and to integrate them into a common culture is proving to be a monumental energy and money draining task. Ask PhyCor or MedPartners or any leader of any major integrated delivery system.

The State of Physician Organizations Today

What's the state of physician organizations today, and why have a "Congress" to decide where medical practice in general and physician organizations in particular are going? To answer the difficulties of answering these questions, you have to understand the states of mind of physicians themselves.

1. Nothing brings you so close to practical realities as being a physician. You entered the world to serve patients and yourself, not a hospital or a business corporation. Your vision of consumers is as individual "patients," as sick individuals who need the best help they can get, even if that help is expensive and experimental. You're the "patient's advocate," their protector and their guide through a world fraught with obstacles to care in hospitals and by specialists. You see patients on a one-to-one basis, and you don't think too much in terms of the "health of the population." You don't think in terms of "EBITA," earnings before income, taxes and amortization, of the investor-owned HMO who profits from your minimizing care or even maximizing health. You realize patients spend 99.9% of their time outside your office, and their health is generally their choice, and rarely rests on your advice.

2. As a physician, you distrust organizations. Your success has always been by dint of your individual effort, whether that effort be getting good grades in college, doing well in medical school to qualify for the residency of your choice, caring for sick patients in academic medical centers or inner city hospitals. Your rewards came through working hard, mastering your specialty, impressing colleagues, not through participating in hospital, HMO, or corporate bureaucracies. In fact, you dislike organizational politics, you're adverse to meetings, and you turn a wary eye towards any activity that takes you out of the operating room, off the wards, and away from your office, for those locations are where the patients and the income is.

3. Besides, what has any managed care or business corporation done for you? You've known for a long time that HMOs manage "cost" not "care." Has any HMO medical director or executive ever helped you care for a patient better? Has adherence to some clinical guideline helped you find the right answer to your patient's problem? Has any managed care organization placed at your fingertips in the waiting room, at the "point-of-service," any easy-to-use information system that saves you time by telling you what drug to use, what diagnosis to consider, and or whether the patient can pay? Not in your experience.

4. Instead, everything that relates to managed care discounts your fees, drives your revenues down, compels you to hire more personnel to deal with HMO clerks or "Doctor Denial" HMO medical directors , and forces you into organizations in which overhead is higher, rules are stricter, income is lower, work is harder, and a production line mentality is at work. For God's sake, you're a professional, not a provider or worker to be ordered about. What do these businessmen and health care executives and their lackeys on the other end of an 800 line know about practicing medicine anyway?

5. Given these states of mind, it's no surprise to me physician organizations resent being owned by HMOs, hospitals, or PPMCs. It's no surprise to me physician undermine their owners. It's no surprise to me business executives are having such a hard time "herding cats," as they so quaintly and demeaningly put it. It's no surprise to me that physicians resist "retaining earnings" to pump into business organizations they innately distrust. It's no surprise to me that lawyers, accountants, and executives are having such a hard time imposing business principles on physicians.

Recurrent Observations

As I pondered this conference's three days, these recurrent observations came to mind that describe the physician industry as it goes through the metamorphosis from a "trillion dollar cottage industry" run by physicians to a business run by professional managers.

First, commercialization leads to balkanization of health care.—The Balkans are countries of the Balkan Peninsula (Yugoslavia, Bulgaria, Albania, Greece, Rumania, and the European part of Turkey.) The countries have a history of feuding, and the term balkanization has come to mean the breaking up of larger states or entities into competing mutually hostile political units. In a sense that is what is happening to American medicine. The so-called House of Medicine is breaking up into competing economic units beholden only to themselves and their bottom line. Most of these units have their own economic strategies, which are "proprietary," trademarked, and not shared with others. The loyalty of physicians practicing in competing organizations belongs to the organization, not to organized medicine and not to a larger specialty. This "balkanization" is not necessarily bad; it's what competitive markets are about and it's why health care is always said to be "local." You act in the best interests of the business corporation who employs you and you act in the best interest of the strongest local health care organization, most often a hospital preaching the gospel of "community solidarity."

This commercialization trend disturbs people like Victor Fuchs, professor emeritus of economics at Stanford University, who applies economic analysis to social problems of national concern. Professor Fuchs gave the opening address at this Congress, and in one of his handouts, an interview with John F. Iglehart in the January/February issue of *Health Affairs*, he made this case against commercialization:

I have always advocated the development of an integrated approach to delivering health care, but I visualized it as being primarily led by physicians and other health care professionals. Instead, it now takes the form of commercialized ventures run by people who have a business approach and who make decisions much as they would in if they were in any other business. This frightens me considerably. Why would business executives running health care organizations behave any differently than those running securities firms or real estate investment schemes behave? Business executives try to maximize profit—that is the business ethic. We risk losing sight of medical care as the expression of a professional ethic.. The corporate mentality judges success by profit growth. Physician-led systems will also have to pay attention to costs, and physicians will also be interested in making a good income. In my opinion, however, there is a vast difference between a profit-maximizing corporation and physicians who strive to balance their obligations to patients, their organization, and themselves.

Second, managed care's here to stay, and even in the face of the PPMC industry collapse, sooner or later it will re-emerge in one form or another because physicians will require capital, management skills, and infrastructure to compete.—Present Wall Street models may be dead, but new models will be re-invented. Here are some of my notes on what was said by those speaking on capital for physician organizations

- ❊ Robert Daly, managing director, MedEquity Investors, Boston: The money is there to fund dominant regional primary care groups and these groups will work if capital firms take a minority position;
- ❊ Efrem Sigel, New Rochelle, New York, Corporate Research Group, which publishes *Managed Healthcare Report, Physician Practice Management Report, Return on Quality Report:* The PPMC industry needs to be re-thought so it will delivery quality care at lower cost and so it will continually improve quality;
- ❊ Douglas Sherlock, president of Sherlock Company, a health care research and advisory firm, and publisher of *PPM:* Future PPM success will depend on maintaining loyalty of physicians and that loyalty will depend on them making more money after than before acquisition;
- ❊ James Hoover, managing partner, Dauphin Capital Partners, Locust Valley, New York: Investment opportunities will continue to exist because the physician practice industry is under-saturated, because capital, financial and market pressures still demand physician consolidation, and because selected strategies—single specialty PPMCs practicing disease management and setting up profitable ancillary centers—will be successful.

Another speaker was Daniel M. Cain, principal in Cain Brothers & Company, LLC, a health-care strategic and investment banking firm with offices in New York, Chicago, Houston, and San Francisco. As part of this presentation, he mentioned an article of his in the October 1998 *Group Practice Journal*. Here is an excerpt from that article, which is right is on target:

Let me share the criteria many health-care venture capitalists now apply in reviewing PPMC funding proposals and what we may have collectively learned from today's low public market valuations. The first lesson to be learned by collective failure of this generation's PPMCs is that outsourcing of management needs, not ownership of physicians' incomes, is the appropriate corporate model.

The goal of any management contract is greater resource efficiency and cost effectiveness. The customer gets value through time savings, consistency of product, and predictability. Likewise, the employee gets higher benefits through working within an organized structure rather than independently.

In the business plans of Joe Hutts (PhyCor's President and CEO) our industry will focus on outsourcing of specific management, technology, marketing, or contracting tasks. The physicians in a medical group displace identifiable existing costs through the outsourcing contract and put in place measurement tools to monitor future deliverables. In this process, physicians need to appreciate that the companies to which services are outsourced need to earn a fair rate of return, otherwise they cannot afford to stay in business. Both parties win only if value is created and sustained.

The second lesson to be learned is substantive product differentiation. A rule of thumb in the venture capital community is the variation of the "80% to 20%" axiom. Eighty percent of the truly innovative and creative new businesses are funded and nurtured by 20% of the professional fund management teams. Being the first of a breed (ie, new fashion product) captures venture capital funding, board talent, and market opportunity. The clones that follow may have a more perfected business plan, but they often get left at the altar.

A third delusion merging from the failures of many PPMCs is the difficulty of nascent company scalability. Does value only result from "franchising" or acquisition growth, or does success derive from competitive advantage resulting from market displacement? The "roll-up" model of many PPMCs captured the fancy of both investors and physicians seeking quick financial success. In my PPMCs acquisitions, however, nothing changed after the acquisition check cleared, except the physicians' motivation and need to work—and the company stationery.

Both Wall Street and Main Street agree the need for physician practice management services and capital resources has not declined. With the hospitals' increasing reluctance to test fraud and abuse interpretations and the managed care companies' distancing, the next generation PPMC will be in hot demand. Part of this demand will be met by existing PPMCs through contract renegotiations and new risk-reward initiatives. New ventures, however will define physician empowerment differently.

Third, physician rejection of investor-driven PPMCs provides hospitals with a historic opportunity to reassert themselves as the "community's and the physician's best and most enduring friends."—Despite all the hype about the rise and fall of PPMCs, hospitals have always been and will continue to be physicians' biggest single financial partner. In those PPMCs that have failed, it seems likely that community physicians will turn to hospitals for support. It also seems probable that the price of buying physician practices has come down, and hospitals will acquire them at a more reasonable price. This was brought out clearly in a talk by Dean C. Coddington and Keith D. Moore of McManis Associates in Denver. The presentation, entitled "Lessons Learned from Research into Hospital-Medical Group Relationships," summarized lessons learned from the field, including lessons from non-hospital partners.

In another talk, Michael A. Wilson, pesident and CEO of the Catholic Health West Foundation, addressed the subject of "The Future of Hospital-Affiliated Physician Organizations." He said physician acquisition had gone wrong because it was a good idea before its time, markets were not ready, and capitation didn't arrive. This was compounded by hospital administrators' inexperience with integration, by the lack of physician motivation to be productive, and overpaying for practices. He noted only 15% of hospitals had positive returns within two years of acquiring practices and that losses per physician acquired were $54,000/physician/year. Despite these losses, he insisted system-sponsored primary care care physicians were valuable for a hospital system and the overall "true value" of a primary-care practice exceeded its negative-cost accounted operating margin.

Fourth, the maxim "Build it and they will come" may work locally for well-established dedicated HMOs, but take it on the road and you may find yourself as road kill.—Here I'm thinking of the $9 billion Kaiser HMO and its 10,000 member Permanente Medical Group. In his presentation, Francis J. Crosson, MD, spoke of the future of HMO dedicated staff models and group models. He said the staff model HMO was largely gone, and the transition was to group and to mixed/IPA models. This transition has been driven by the need for speed to adjust to market changes, the capital baggage and high fixed expenses of staff models, the incessant purchaser demands for choice, the difficulties of reducing incomes of long-time Permanente physicians, and the lack of market responsiveness to staff model plans. He also noted the uneven growth of Kaiser nationwide, and the pulling out of Kaiser from the Texas market. Although Permanente has over 10,000 salaried physicians and its national HMO membership is over nine million, it is now losing money for a number of reasons and is having difficulty expanding in regions outside of California. Its physicians need to access capital outside of Kaiser itself, and there are tensions between the HMO and its medical group. This year Kaiser Permanente, the nation's largest HMO, recorded a third-period loss of $102 million and expects a full-year loss of about $266 million. Kaiser is grappling with pressures of rising medical costs, including pharmacy and medical technology, and increased demand for services.

Fifth, the market and consumers have no respect for world-class icons. The market wants low costs, and the consumers want friendly world-class service. Being a legend in your own mind and in the world of academic medical centers carries very little weight.—You would think that with a name like Harvard, a medical group would have the world as its oyster. But Harvard Vanguard Associates is having its problems despite it close affiliation with Harvard Medical School and its teaching hospitals.

Vanguard has elected to contract only with the Harvard Pilgrim HMO through 2000, but realizes it must move from a staff-model HMO to a group HMO. It no longer has a price advantage over competing HMO-IPAs. The clinicians in Harvard Pilgrim split off from Harvard Pilgrim because they realized the interests of the Harvard clinicians and the health plan were no longer identical. The clinicians also were aware that "the staff model HMO was dead," and they would have to make tough decisions on compensation, life style, and practice style to appeal to an increasingly consumer driven system. This meant they would have to personalize their services to patients. The goals of Harvard Vanguard are:

1. Build stronger personal relationships with patients so they speak of "my doctor," not "I go to Harvard Vanguard."
2. Increase clinician productivity, thus improving access to care and lowering costs
3. Develop a distinct identity from Harvard Pilgrim, so patients identify us as a clinician-governed group practice, not an HMO.
4. Generate sufficient capital to permit us to be independent of Harvard Pilgrim or any other health-care organization.
5. Differentiate ourselves from other high-quality providers by being leaders in supporting "patient mastery."

The "patient mastery" concept has evolved rapidly in the highly educated high technology Boston market, where many consumers have internet access and little time to tolerate long waiting times, inconvenient care, and insufficient answers. Patients want to be the "masters" of their care, and among them, there is an erosion of trust, growing demands by Baby Boomers, an increasing knowledge of "what works," the "liberating" influence of information and communications technology, a sense of "time bankruptcy," and incessant pressure to diversify into such things as alternative practice options.

Sixth, the practice management industry may go underground for a time, eg, PhyCor may go "private," but it will inevitably resurface in another form.—In his presentation, Joe Hutts, President and CEO of PhyCor, spoke not of the PPMC industry as a whole but of the "strong economic fundamentals" of PhyCor. Later, in a press release, Hutts said PhyCor, which has lost three-quarters of its value, is considering going private. When the company announced it was having trouble integrating physicians into larger groups and took charges against earnings, investors drove down its market value from $2 billion to $500 million. Hutts said he had talked to about a half-dozen firms about going private. James Hoover, of Dauphin Capital Partners in Locus Valley, New York, another speaker at the Congress was quoted as saying of the going private option: "Almost across the board, investors have given up. Why sit there with a languishing stock and take all the heat with no reward? You might as well take it private, especially if you have the cash flow to support the debt service." In his talk, Hover said he still felt substantial market opportunity existed for PPMC and he anticipated a slow market recovery with investments in single specialty PPMCs and in physician practice management outsourcing businesses.

Seventh, for winning health-care organizations, winning physicians' loyalty and respect through superior financial performance will be the principle ingredient for success.—According to Douglas Sherlock, publisher of PPMC Analysis, loyalty to a PPMC depends on whether the physicians is better off after the transaction after the acquisition than before. Here are Sherlock's words: "Successful PPMCs can be measured with a simple test that is logical but challenging. *Do the physicians make as much or more money after their practices have been acquired than before?"*

Eighth, information technology systems may be hyped as the Holy Grail, but there is no system out there yet that glues together and integrates hospitals, physicians, payers, vendors and consumers—Information systems are essential, but they are still primitive works in progress. Information systems may well hold the ultimate answers to efficiency, effectiveness, and profitability, but we're not there yet.

Ninth, the clamor for access to technology and choice will drive up costs.

Tenth, government reform in the name of stamping out fraud and abuse will increase costs of doing business, will create the compliance industry, will result in a new breed of executive cat known as The Chief Compliance Officer, and will be a bonanza for health-care lawyers.

Eleventh, there is no "perfect model" for every region of the country; the model depends on politics, culture, and the business environment, and what the consumers want —what works in California and Minnesota may be irrelevant for the rest of the country.

Twelfth, managed care as envisioned by its architects, namely prepaid care through managed competition, simply will not work because it isolates and insulates consumers against the true costs of their care; a new model, perhap, like the one now offered to nine million federal employers through Federal Employees Health Benefits Program (FEHBP), in which the government offers a defined financial benefit and lets employees choose whatever plan they want and lets them pick up the difference in costs, is a logical and proven model.

Conclusions

- The American health care system remains a $1 trillion dollar "cottage industry" in that most doctors still aren't organized into large groups or networks; instead 60% are in groups of three or fewer, and those in solo, small, and large groups are beset and besieged by forces pulling them in different directions—the government is decreasing reimbursement, managed care is raising premiums, consumers are demanding more not less services, prescriptions drug costs are skyrocketing, groups are spending more to meet compliance standards, politicians are demanding "reform," costs are escalating from every direction, and doctors are sitting on the sidelines.
- There isn't any dominant and successful physician organization—staff-model HMOs, multispecialty groups, single specialty groups, IPAs, MSOs, PPMC, hospital driven systems, or small or solo practices. All have their advocates and true believers. Each have their defenders. And some, such as IPAs in the West, work better in different markets. Much of the old collegiality is gone in metropolitan markets with significant surpluses.
- If there's one consistent theme among physician organizations, it is this: physicians can't depend on white knights such as PPMCs or hospitals to bail them out, and physicians are going to have to depend on their own wits, their own discipline, their own resources, and outsourcing to administrative task to survive.
- Certain demographic, market, and political forces are at work—an aging population, demand access to technology, consumer activism by Baby Boomers, and American outrage at denial and rationing of care —that will be difficult to control.
- No central organization—HMO, hospital, PPMC—is strong enough to subjugate or win the loyalty of physicians, or is politically astute enough to figure out a model that contains, corrals, or channels physicians into doing what that organization thinks needs to be done. Ownership of physician practices or income has failed in all settings.
- The ultimate answers to efficient physician organizations will lie in physician ownership, accountability for budgets and standards, and outsourcing capital, management, and infrastructure to other organizations.
- Managed -care payers and markets respect no organizations—no matter how big, prestigious, or quality-perceived or quality-measured. Harvard, Scripps, Mayo, the Cleveland Clinic, Permanente, Duke University, the University of Pennsylvania, and other big multispecialty or academic centers are in actual or potential financial troubles because of dropping reimbursements or consumer flight. The market is impersonal and respects no incomes. It respects only consumers, competitive premiums, and profits.
- Staff model HMOs—Harvard Pilgrim, Kaiser Permanente and Group Health Cooperative—are stagnant in their growth and losing their appeal to consumers. Commercial pressures are forcing these staff models to diversify, to reach out to non-plan physicians and non-plan hospitals, and may even compel physicians within these plans to separate themselves from the mother HMO to retain their professional identity and to gain access to other sources of capital.
- Physicians are becoming increasingly militant as they become more embattled and more salaried, and the physician union movement, the resignation from HMO panels, and rebellion, detrain, and suing of PPMCs is all part of this militancy.
- Much of the noble rhetoric supporting the managed care movement—improvement of the health of the population, systematic prevention of disease, coordination of care, seamless delivery of care, rationalization of care, quality or value driven care—is curiously absent at a meeting like this. Consumers and physicians either aren't yet buying the message in most markets. Payers remain transfixed by price. What both the consumer and physician constituencies want is personal, confidential, and patient-advocacy care without intervention by large managed care organizations.
- Those organizations "owned" by physicians which allow them to remain in private practice in the "neigh-

borhood," or which have community-wide presence, such as IPAs, are growing stronger rather than weaker.

- Large multispecialty clinics with long traditions, such as Mayo, the Cleveland Clinic, and Oschsner, will survive by consolidating or buying up their local referral sources, but they too face formidable economic pressures and challenges from onerous government regulations, decreased revnues, skyrocketing costs, especially pharmacy costs, and new consumer demands.
- Multispecialty PPMCs are in a tailspin. Many will be sold off, closed, or merged. Physicians in surviving PPMCs may take a 15% to 20% pay cut.
- Hospitals are in good shape. Margins remain at 5%. Bed days have bottomed out or are growing slowly. Hospitals are still buying practices, about 5,000 per year, and physicians are looking them as more reliable financial partners in wake of PPMC collapse. Voluntary hospitals have long argued that they are essential for "community solidarity," and that they will be there long after the "Wall Street Wonders" are gone. Right now "we bring value and we'll always be here for the good of the community" is a winning message. So is the message that "PPMCs bring no value to the community," "value" in this case being code language for not helping physicians economically or improving access or quality of care for local citizens.
- Managed care in general and Medicare risk in particular are in a highly uncertain state. Contrary to popular wisdom, managed care has peaked or is even receding in many major markets.
- Consumers are driving change right now, and they want access to "my doctor" and not to "my integrated health-care system" or "my HMO." Consumers and voters blame Fraud and Abuse for health system problems, and their political support is driving "health reform." The mass withdrawal of 96 HMOs from 440,000 Medicare constituents is increasing skepticism among Americans for managed care and bodes badly for the PSO movement.

Summary

Integrated medical groups.—Growing in size and number through mergers and acquisitions. But growth is slow and painful because it's difficult to integrate the cultures of solo and small groups into a single large organization. When overhead goes up instead of down, and when incomes fall, rebellious physicians either undermine the new organization, become non-productive, or pull out. Some integrated groups, even large well-established groups, are shrinking rather than expanding. Physicians balk at the costs of bringing in new doctors and new executives and new systems. These costs may run in the neighborhood of $50,000 per doctor per year.

Independent practice associations.—Growing in size and number and sophistication. Physicians like IPAs because they retain practice ownership, location, and autonomy; Consumers like IPAs because they can often see "my doctor," who is often a specialist. Regional geographic distribution is a key appeal. And corporate payers like them—their employees are often satisfied, because of competitive premiums, and because of increasingly sophisticated management and infrastructure.

Group/IPA hybrids.—Growing for same reasons as IPAs, but more attractive to some payers because of managed-care expertise of anchor groups

Tax-exempt groups.—Stagnant in overall growth. These groups tend to be confined to the West.

Physician practice management companies.—Current number of publicly traded companies, 32, expected to shrink by one-third, and 200 private PPMCs will also decrease through mergers, withdrawals form IPOs, and capital failure. MeCath has gone "private," and many think PhyCor will follow. Specialty PPCs remain viable, and certain models that are relatively immune to managed-care pressures, eg, Pediatrix, Kelson Pediatric Partners, Women's Health Partners, and Ortholink, and dental PPMCs, are expected to grow.

Hospital-based groups.—Forecast is mixed. Hospitals are still acquiring primary-care practices at rate of about 5000 a year, but some hospital based groups are being closed, others are being spun off, and still others are being redesigned with either lower physician salaries and incomes based on productivity.

HMO staff models.—Dead, dying, or diversifying into group models. Many clinicial groups, formerly salaried employees of HMO, are breaking away from the mother HMO to form independent groups with their own identity and with the ability to access capital from sources other than the parent HMO.

Physician-owned health plans.—Most are not doing well, and a few, such at California Advantage, have filed for bankruptcy. Others are being sold to commercial HMOs. Significant problems are underestimation of capital needs and management and marketing expertise. Also physicians who form such organizations are often anti-managed care and attract high-users of medical services.

Physician-unions.—Growing rapidly among certain groups—employed physicians, residents, and government physicians—but not among self-employed physicians. Among America's 750,000 physicians, 45,000 or 6% belong to unions. Factors favoring union growth among physicians are loss of confidence, seeking of shelter from economic realities, anger at third-party payers, and physicians viewing themselves at industrial employees rather than professionals. Physician unions will probably not become commonplace because government is initiating anti-trust actions against physician unions, expense of union formation, expense of collective bargaining, and controversy whether physicians are managers or employees.

Academic medical centers and faculty practice plans.—Perhaps no type of physician organization is struggling more than academic medical centers. These centers tend to be tertiary centers, saddled with costs of teaching and research, and burdened with expenses of caring for inner-city poor. The more aggressive centers, such as Duke, the University of Pennsylvania, and Harvard, are cutting costs, acquiring practices and hospitals, reaching out to the community, beefing up their primary care residencies, stepping up their marketing efforts, stressing their ambulatory centers, and positioning themselves as one-stop Integrated Delivery Systems. In some cases, setting up their own HMOs. Results are mixed. The University of Minnesota hospitals had to sell to a community hospital system, and the huge Allegheny system in Pennsylvania had to go into bankruptcy. Some have suffered heavy losses from acquired practices, and resistance is stiff among university specialists, who regard bowing to market demands as giving into the enemies of excellence, research, and teaching.

The American Medical Association.—Because it is a political organization representing about 300,000 physicians—fee-for-service, salaried, and HMO employed—the AMA has experienced problems being everything to everybody and serving as a vehicle for business advice. For many physicians, who feel besieged by managed care, the AMA services are too ethereal and political to be useful in a business sense. However, things are changing at the AMA. It is beginning to develop specific, accessible outreach services for beleaguered physicians and to bring tangible and practical business services to its members. The sleeping giant is starting to stir, but whether it can awake fully enough to supply enough members with enough useful and practical services to build membership remains to be seen.

Epilogue

Today's 11 November *Wall Street Journal* carries the news that MedPartners, the giant $6.3 billion dollar PPMC, is abandoning its 238 clinics with their 10,000 affiliated physicians. MedPartners is withdrawing from the industry it helped create. It will sell the clinics back to shareholders or to other companies. This stunning announcement pounds the final nail in the coffin of the investor-owned physician practice management industry.

This collapse comes at a time that other physician practice ownership models—hospital-acquired practices and HMO-owned staff models—are in disorderly retreat. These events signal the dawn of a new era in medical practice and physician-practice management, an era in which physicians will own their practices but outsource administrative functions.

Ownership is the only proven practice model among physicians that evokes the pride, professionalism, productivity, accountability, entrepreneurial spirit, and drive towards practice and product differentiation in their own markets. This new model, however, will require that physicians give up control of certain infrastructure, information, and administrative functions.

What is described above validates the position of the American Medical Association that the practice of medicine is a professionally-driven enterprise that does not operate by the same set of rules or ethics as business. Physicians need business expertise but not business ownership. Consumers need assurance that physicians are still captains of the clinical ship.

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Commentaries

Further Thoughts on a Sustainable Medicine

Ruminations and commentary on the future of a tolerable and ethical medical practice.—When Bob Massey published his two recent editorials in *Connecticut Medicine*, on Daniel Callahan's *False Hopes*, a broad and responsive chord was struck in me, and I wrote to Bob, hopefully renewing a conversation that had been quiet for too long. Dr. Massey answered me, and suggested that I expand my remarks, which initially focused on the best way to a single payer-system—which I have long advocated. I was impatient with his suggestion that we would have to muddle through to get there, although I suspected, even hoped, that he was correct. And I was quite prepared to write as scathingly as I could, how really awful insurance company executives and their micro-managers were, and the politicians who tacitly condone them—even those who are not owned by them. But then something happened to me. I got downsized. The company that I was working for was purchased, and in a move, ostensibly, to reduce costs, my position was eliminated. Now a victim of the very avariciousness I had been denouncing, I should have been even angrier. I was, and I wasn't. These people, probably like many others in the nonmedical for-profit part of our world, are not nice. They are bottomfeeders that deserve every epithet that we can toss their way. They could care less about sick people with problems, who are, as they say, "costs." But what is new about that? That is no surprise. As I began to think about it, I began to understand that they aren't the problem. The problem is the money. It's Willie Sutton all over again, and it's the good old American way—"Go where the money is."

The money is the problem for several reasons. It attracts the for-profit riff-raff, but it also cries for limits and regulation, when someone, anyone, it would now seem, decides too much is being spent. It's a lot like taxes; everyone is against them, until they want something. Everyone derides and denounces the medical care expense, but wants no corners cut when it comes to their own care. But the problem is really ours, because we control these expenditures. We decide just about everything about medical care spending, in the final analysis, and will not regain any control over our profession, until we begin to understand this and act responsibly regarding our fiscal world. This is, of course, obvious, but I mean to suggest that our responsibility is far greater than ordering or not ordering expensive and/or useless tests or drugs, or choosing inefficient therapy, or charging too much, or not caring for the poor or rejected, or not doing enough prevention. Far greater, and far more complex, is our involvement in a culture that has deified medical science, denied death and suffering, demanded instant and perpetual satisfaction, and been more than willing to spend almost every last dollar in a vain attempt to achieve it.

We are a part of this culture; we have grown up in it, and most of us believe in its values implicitly, if not explicitly, and we sell and support it. Callahan argues, I believe, incontrovertibly, that this system is at once unrealistic and dangerous. It is based on premises that do not withstand, as they say in the academic world, rigorous analysis. It is based on dreams, and hopes, and denial, and we all participate in it. We believe that we, as physicians, really prolong meaningful life; we believe we cure cancer, well, occasionally; we believe our world is a better place for what we do; and we sell ourselves, our science, our "magic," continuously. As if we would have to. Our patients, the media, the entire society gobble it up, and ask for more. An article in the *New England Journal of Medicine* suggesting a minor incremental improvement in the management of some incurable problem is given first-page status and embellished and distorted on the evening news. And we do not question whether this makes sense. We too rarely wonder if the expectations are out of hand.

In our hearts, where we must finally decide what will happen to us, we must know that all is not as we want it to be. We must suspect that it never was, and very likely never will be. We must begin to wonder how could we have become so arrogant, when all the time we were becoming more ignorant. It is very hard to think about this, for it involves, at least for me, the basic values that have guided my life for most of its duration. We all joke about the old Walt Kelley–Pogo aphorism, about meeting the enemy and discovering that it is us, but that is just what is going on, and what we must deal with. I would not attempt to summarize or distill Callahan; rather I would urge every one of you to read, really read, then think about and discuss his book, but I would ask you to think hard about several of his basic tenets.

Consider what is a meaningful life? Ask yourself how you want yours to end? Many of us have already dealt with this with our parents. Did we authorize the third generation cephalosporins for the third pneumonia in three months? Did we really believe the aricept helped? Did we insist that our 90-year-old grandmother take her statin, ACE inhibitor, beta-blocker, and aspirin, even though she couldn't remember her heart attack? Did we agree to the marrow transplant, or the dialysis, because it might help, and might not prolong misery, although it was far more likely really to hurt a lot, and help very little? My guess is that most of us come down on all sides of these kinds of issues. They are complex, scientifically, ethically, and usually very individual. For most of us, there are seldom absolute rights or wrongs. But I think there is a great deal of discomfort stimulated by trying to deal with these issues, and more often than not, we opt for the technology, because it is easier than accepting our limitations. Where is it written that man is immortal, that even if mortal, everyone must live as long as science and technology can stretch him out? Of course, nowhere! But we just don't want to believe it. We'll keep her alive another day, or week, or month, whatever, and maybe a miracle will come along. Nonsense. We know better, but we don't act that way.

And, what is our primary mission, curing or caring? It is written in a lot of places that we should comfort, but do we do it very well? I don't think so. I know, personally, that I want to be optimistic, to offer hope. I do not like being the naysayer, the speller of doom. None of us does. Too often when we should be painting a difficult and painful picture of someone's future, we are offering false hopes, and unrealistic scenarios. We lose opportunities to console and comfort, and begin realistic planning. And I think we feel guilty that we can't do much good, and then in our arrogant angst, forget all about the poor soul whose misfortune we are dealing with in the first place. I have been in medicine long enough to recall those times when we didn't have so much to offer people. People with renal failure died, or survived miserably on awful diets, with a terrible cacophony of symptoms. End-stage diabetes wasn't any better. Cancer was resected, and radiated, but unless these were successful, seldom cured. A heart attack was a major event, with no one daring to imagine it might be limited or repaired or prevented. Had someone suggested that a cirrhotic patient's liver be transplanted, whether he had stopped drinking or not, he would have been hooted out of the room. Yet I'm confident that we took very good care of these very sick people. We did the best that we could, and our work was valued and respected, by our patients and ourselves.

But, of course, we all wanted to do better. We were frustrated that we could not save, or cure, or fix, whatever and whenever these new treatments and techniques came along, we jumped at them. I did, I know, and I believe we all did. It seemed so right—we were helping. Conditions that had never gotten better, began to, and it was wonderful. It was, but we were not wise enough to exercise caution, to reflect upon the more complex aspects of our progress. Those of us that did, were ignored, or brushed aside in the tidal wave of breakthrough and promise. And as we jumped on the bandwagon, we forgot why it was so attractive in the first place.

I was fortunate to participate, as one small part of a team, in the work that demonstrated that combination chemotherapy could produce lengthy remissions and ultimately cure in previously untreatable and ultimately fatal cancer. One cannot describe well enough the incredible feelings occasioned by seeing a patient one's own age with a heretofore fatal disease (Stage IV Hodgkin's disease) going into a lasting satisfying remission. That was a high! The toxicity seemed mild enough and well enough tolerated. Why not try it in leukemia? And it worked there, too, but not quite so well. And then this cancer, and that one. We are still at it, but 30 years later we are not much better at it. Why? Many reasons. Mostly not enough knowledge or unwise use of that we had. But also our arrogance, our failure to understand that this good try was only that. We were doing better, but we were not winning any war. Meanwhile, we ignored the nonresponders. We minimized the toxicity, denied the complications, even the suicides in failed patients. We were not wrong, we were not bad people. But we were obtuse, and insensitive, and we lied. We told people that we could "cure" them, when we should have tried to explain the probabilities of prolonged survival. We held press conferences for every tiny incremental advance—we still are doing that, and promised something we should have understood we could never deliver. So individually and collectively, in our offices, and in our press releases, we convinced ourselves and our public that we could cure cancer. Nowadays chemotherapy is a norm; it might almost be malpractice not to offer it. As I write this I am thinking of a 90-year-old patient who has an obstructing metastatic stomach cancer and is recovering from a bypass gastrojejunostomy. For the first time in months she is able to eat and she is regaining strength rapidly and feeling stronger. Her surgeon and her family are strongly recommending chemotherapy. I ask why, and what for, and get funny looks. She is wiser than the lot of us, and will likely say no. "Ninety years is enough," she says, "I am fortunate to have been well so long, and now to be well, again, if just for a short time, is a blessing. Enough is enough."

Oncologists do great things. I do not argue that. But I don't think they always make the obvious or subtle distinctions and choices that used to be what doctors did. The problem I think for all is the discomfort that limitations cause us. It is always difficult to admit that one doesn't know, but it seems to be even harder to acknowledge that one can't. But we can't. People die of cancer, and heart disease, and infections, like they always did, unless they run into the other products of our technology, cars, guns, and drugs. Cardiologists don't cure heart disease either, but they thrive on it. I pick upon my fellow internists, but we are all guilty, even the purest of pediatricians promises more than he can deliver.

So we have paved the road with good intentions, and some progress, and a lot of publicity, and convinced everyone, including ourselves, that this was the way to go. Along the way we found that we could be well paid for doing this, and did not stop to ask if this was equitable or appropriate. We also learned that it was better not to ask such questions, and we tolerated excess and waste. Most of us found rationalizations for ignoring the needy. The journalist Haynes Johnson titled his book about the Reagan years, *Sleepwalking through History*. That is what, I fear, the medical profession has been doing, for too long. But we are awake now. The wake-up call was harsher than we had anticipated. What happens next?

Short term it is pretty clear, and terribly depressing. Everyone will scream, and squeeze, and the bands will tighten. Less recompense, fewer options, more regulations, and ever increasing despair. Sooner or later most will figure out that insurance companies, one, can't make enough money at this, and two, run it very badly, and they will bail out looking for another enterprise that seems to have excess money, and head off to rape and pillage that. People will also continue to assume that government can't do it (wrongly, I think. For example, Medicare is heaven compared to a for-profit insurer, these days, even if it pays "poorly,") and that politicians can't be trusted anyway (probably rightly.) Who can or will they then turn to? It could, it should be, the medical profession. But if they do, we need to be ready. And this time we need to be honest. We need to be able to say we cannot cure you of every disease. We need to say that we will all die, hopefully in our 80s or 90s after a reasonably healthy but not perfect life. We need to say we can help you achieve this, but we cannot and should not do everything. We do not have the resources or the knowledge. But, most things do get better by morning. You can take good care of yourself. You have a very good shot at a reasonably long and healthy life—particularly if you wear seatbelts, drive reasonably, and do not have a gun in the house. We need to say we are in the same boat, we share these realities, and we can help you through it. We will be sure everyone is cared for, and our fees will be fair. And we need to really mean it, so people will understand their expectations will need to be lowered, and made more realistic.

Several years ago George Annas proposed a different model for medicine's relationship to society. He suggested an environmental approach for managing limited resources. This he opposed to the doomed current military paradigm—the waging a war on death and disease mentality. We are losing that war; a war we should never have started, and could not have won in any case. Let us acknowledge and accept our limits, manage our patients, and our resources accordingly, using them wisely. We can not be all things to all people, ut we could do so much for so many of them, and insure that all have our care. This is the "sustainable medicine" that Callahan and Massey are writing about. It is possible, but more important, it is necessary. Are we ready to consider it?

Wesley M. Vietzke, M.D.
Branford

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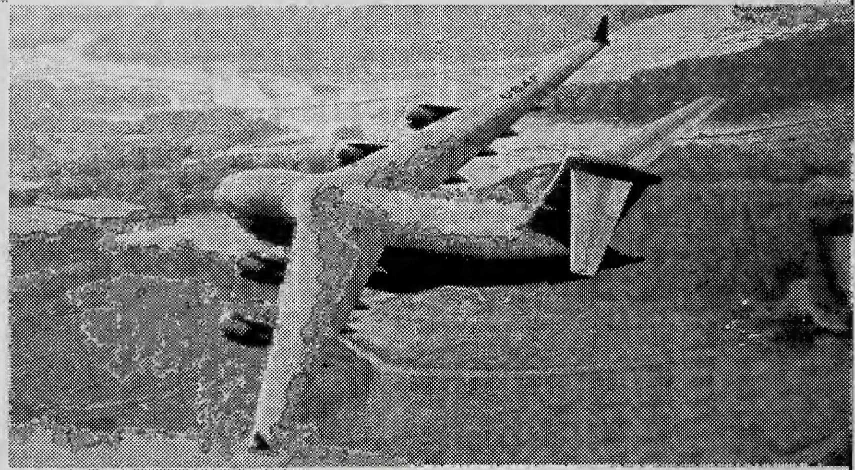

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50 Years Ago

From *The Connecticut State Medical Journal*

December 1948

Dr. Senn New Head of Yale Child Clinic

President Charles Seymour of Yale University has announced the appointment of Dr. Milton J. E. Senn as director of the new Yale Child Study Center.

The new center will include the Yale Clinic of Child Development which was established by Dr. Arnold Gesell. Dr. Gesell retired as professor of child hygiene on July 1.

Dr. Senn comes to Yale from his post as director of the Institute of Child Development and professor of pediatrics in psychiatry at the Cornell University Medical College. At Yale, he will be Sterling professor of pediatrics and psychiatry.

The new Yale Child Study Center will help to guide parents, teachers and other persons concerned with the problems of children. It will contain a guidance nursery, film library and clinical resources to supply research and teaching media for students from professional disciplines interested in the growth, development, behavior and personality of human beings. It will expand facilities for graduate work and research.

Dr. Senn has shown that the pediatrician must be trained not only in the field of medicine in order to treat illness but also in the field of psychiatry to understand the relationships which every child has with his parents, teachers and others. He also has brought to people in the field of psychiatry a new insight into pediatrics.

He is the author with Phyllis K. Newill of a book, "All About Feeding Children," which was published in 1944 and has written articles for scientific journals on the relationship of psychiatry to pediatrics, pediatric education, and the management of sick children.

Born in Milwaukee, Wisconsin, he received both B.S. and M.D. degrees from the University of Wisconsin. He received his intern training at the Columbia and Milwaukee Children's Hospital from 1927 to 1929 and during the next year was an intern and fellow in pediatrics at the St. Louis Children's Hospital in St. Louis, Missouri.

From 1930 to 1933 he was an instructor in pediatrics at Washington University in St. Louis and from 1933 to 1939 served as an associate in pediatrics at the Cornell University Medical College. From 1937 to 1939 he served as a Commonwealth Fund Fellow in psychiatry at the New York Hospital—Westchester Division and the Philadelphia Child Guidance Clinic.

He was promoted to assistant professor of pediatrics (psychiatry) at Cornell in 1939 and in 1942 to associate professor of pediatrics in psychiatry. He was made director of the Institute of Child Development at Cornell University Medical College last year and was promoted to full professor.

He is a member of The American Pediatrics Society, The American Psychiatric Association, The American Academy of Pediatrics, and the New York Academy of Medicine.

Dr. Gesell Heads Child Vision Research Project

Dr. Arnold Gesell, one of the world's most prominent authorities in the field of child behavior who retired as director of the Yale Clinic of Child Development on July 1, will continue his research at the University in charge of a Child Vision Research Project.

Work on child vision has been carried on as part of the general program of the Clinic of Child Development, in close association with its Guidance Nursery and Diagnostic Service for the past four years. It is supported by a grant from The American Optical Co.

Reprinted from the *Connecticut State Medical Journal*, December 1948.

At Yale, the normal development of visual functions in infants and children is being explored by means of periodic examinations during the first ten years of life. The investigations are concerned especially with the growth aspects of vision and associated behavior.

During the current year the major research will be continued by Dr. Frances L. Ilg and Glenna E. Bullis under the direction of Dr. Gesell.

Author of two dozen important volumes on child psychology and child growth, Dr. Gesell holds both Ph.D. and M.D. degrees. He has been a member of the Yale faculty since 1911 and has been a Professor of Child Hygiene since 1915. In addition to publishing numerous volumes on normal and defective children, exceptional children and their education, handicapped children in school and court, mental growth of infants and children, learning and growth of identical infant twins, treatises on experimental psychology, and an atlas of infant behavior, Dr. Gesell established in 1925 the photographic library of the Yale Films of Child Development. He has supervised the production of scientific and educational motion picture films at the University since 1930.

He holds an honorary Doctor of Science degree from Clark University and was a member of the White House Conference on Child Health and Protection and the White House Conference on Children in a Democracy. He served as school psychologist for the Connecticut State Board of Education from 1915 to 1919 and as a member of the Connecticut Commission on Child Welfare from 1919 to 1921. He is a member of the Connecticut Society for Mental Hygiene and a Fellow of the American Association for the Advancement of Science, the American Medical Association, and the American Orthopsychiatric Association. In addition, he is a member of many national medical and scientific societies.

Drs. Fulton and Winternitz Receive Awards

John F. Fulton, Sterling professor of physiology, and Milton C. Winternitz, professor of pathology, were among eight Connecticut scientists and engineers, five of them Yale faculty members, recently to receive the award of the President's Certificate of Merit for important contributions to national safety during World War II. The awards in New Haven were part of a nationwide recognition of the scientists and engineers who contributed their services through the Office of Research and Development. The distinction of their services is hinted in the citation in recognition of "a contribution to our joint safety and future greatness beyond the ability of most men to achieve."

Dr. Fulton was cited for his six years of outstanding services in the field of aviation medicine. He was chairman of a committee on decompression sickness and served on a committee charged with the study of the whole field of aviation medicine. Dr. Winternitz was chairman of a committee on treatment of gas casualties as well as chairman of two other important committees.

Dr. Blumer Honored

The staff of St. Raphael's Hospital on October 5 feted Dr. George Blumer, outstanding clinician and an attending physician at the hospital until his recent retirement, at a testimonial dinner in the Lawn Club. Dr. Blumer now lives in California.

Coming to New Haven in 1907 as a professor at the Yale Medical School, Dr. Blumer was dean of the school from 1911 to 1921 and from 1921 to 1945, clinical professor of medicine there. 10 years ago he was considered one of the 10 outstanding American physicians.

Author of numerous monographs in clinical medicine, Dr. Blumer edited the well. known "Foreshiner's Therapeutics" and "Blumer's Bedside Diagnosis." He also has been a frequent contributor to the *Journal*, his editorials appearing over the initials "G. B."

Report to the Semi-Annual Meeting of the CSMS House of Delegates

(The following report was given to the Semi-annual Meeting of the CSMS House of Delegates, on 19 November 1998, by the president.)

Since the last meeting of the House of Delegates, the Council, its committees and the staff have been very active on a number of fronts. Time does not allow me to go into all of them but I would like you to hear the highlights.

The most significant project we have started since the annual meeting is American Medical Accreditation Program (AMAP).

Those of you here this morning heard a full presentation by Dr. William Jessee, vice president of Quality and Managed Care of the AMA, assisted by Mr. John Copp, manager of AMAP sales. I encourage you to join AMAP and keep physician credentialling and quality oversight in the hands of physicians where they belong.

The Legislative Committee has met several times to outline our strategy for the upcoming legislative session. I will defer to Dr. Parke to report on those deliberations.

The Committee on Ethical and Judicial Affairs recommended and the Council adopted a new policy on conflicts of interest for members serving on the Council. The policy is modeled very closely after the one in use by the Board of Trustees (BOT) of the AMA. The policy was published in the October issue of *Connecticut Medicine.*

Speaking of *Connecticut Medicine,* long-time editor, Dr. Robert Massey, announced his retirement as of the first of the year. The officers met and, with the concurrence of the Council, appointed Dr. David Crombie of Hartford as the new editor. On behalf of the Society, I would like to commend Dr. Massey for the outstanding job he has done for so many years.

With the concurrence of the Council, I appointed a task force to investigate issues surrounding in-office surgery. The CHA would like physicians' offices to fall under the same regulations and require the same certificates of need that the hospitals do. The task force is working with input from several of the surgical specialties to define what are appropriate procedures to be performed in the office. When that is complete, the task force will make recommendations regarding the best way to educate legislators and the public about the safety and cost-effectiveness of in-office surgery.

After meeting with the president and executive director of the Connecticut Nurses Association, I appointed an adhoc committee to meet with representatives of that organization in an attempt to find common ground on the issue of independent practice by advanced practice registered nurses (APRNs). The physicians in attendance all felt that the nurse practitioners in attendance were not interested in compromise but were simply looking for concessions. I have since been informed that the CNA staff felt the meeting went well and they would like to meet again. In the spirit of collegiality, I am willing to meet again but I fear that it will be business as usual on this issue at the state legislature.

Tim Norbeck and I also met with Nancy Najarian, president of the Connecticut Academy of Physician Assistants and Bill Kohlhepp, president-elect of the American Academy of Physician Assistants. Bill is also from Connecticut. Both Nancy and Bill indicated their desire for their organization to become more closely affiliated with ours. They maintain a lobbying presence in Hartford and our organizations can mutually benefit from making common cause there. We will continue to explore ways to increase cooperation.

Reviving a tradition, I met with the county presidents in July to discuss issues of common concern. Tim and the county executives were also in attendance. The topics of most concern were 1) the relationships between the counties and CMIC and 2) the CSMS-IPA and its relationship with MD Health Plan. At the request of the county presidents in attendance, a subsequent meeting was arranged between them and Dr. Ahamed, representing CMIC. There was frank and open discussion by all involved.

In addition to being active in the legislative arena, the CSMS has been active in the judicial arena as well. We have filed an amicus brief in support of an appeal of a recent court ruling which threatens the immunity of physicians involved in peer review. If allowed to stand, the ruling would have a chilling affect on the ability of physicians to participate in peer review without that review being subject to discoverability by an aggrieved colleague. We have also filed an amicus

Continued on next page

brief in a case involving the use of lasers by nonphysicians. The Thermo-Lase Corporation has filed an appeal from the decision of the Connecticut Medical Examining Board declaring that the use of lasers for hair removal is within the scope of medical practice. Our brief is in support of the Medical Examining Board's declaratory ruling. *(The Thermo-Lase Corporation has since withdrawn its appeal and the Board's ruling stands.)*

Two weeks ago Tim, Cam Staples, Michele Norbeck, and I met with Aaron Bayer, deputy attorney feneral of the State of Connecticut and his assistants regarding another court ruling which might negatively affect physician peer review. Mr. Bayer was receptive to our concerns and agreed to establish a mechanism by which the State of Connecticut can become involved early in cases in which physicians are sued for alleged acts arising from reporting on impaired colleagues as required by state law. Commissioner of Health, Stephen Harriman arranged the meeting and he supported our position.

Next Tuesday, Dr. Nancy Dickey, president of the AMA, will be speaking to the Middlesex County Chamber of Commerce's Monthly Breakfast Meeting. Nancy is a dynamic speaker and, if you are available on Tuesday, speak with Mark Schuman of Middlesex County Staff and he can give you more information. Following her speech, Jeff Herter, president of Middlesex County, and I have been invited to participate in a panel discussion entitled, "How Are Your Health Care Dollars Working for You?" Others on the panel will be leaders of HMOs and representatives of business and industry.

In closing, I would like to recognize the personal achievements of some of our members and dedicated staff. Tim Norbeck continues to serve on the Federation Coordination Team, a group begun by the AMA in an attempt to harmonize the extended House of Medicine in whatever ways possible. Cam Staples, our legal counsel, was recently reelected to the Connecticut State Legislature for his fourth term. Art Schuman, executive director of New London County Medical Association (NLCMA) and also executive vice president of the Connecticut Academy of Family Physicians (CAFP), was recently honored as a super-hero of family medicine in recognition of his contributions over his 40 years with the Academy. Dr. Al Herzog of Hartford County was recently elected speaker-elect of the Assembly of the American Psychiatric Association. Dr. Neil Brooks of Rockville, alternate delegate to the AMA and current chair of the board of the AAFP, and a member of the AMAP Specialty Advisory Committee and Federation Advisory Committee, was appointed by AMAP to the Performance Measurement Coordinating Council, a collaborative effort launched in May by AMAP, Joint Commission on Accreditation of Health Organizations (JCAHO), and National Committee on Quality Assurance (NCQA) to coordinate important aspects of performance measurement activities across the entire health-care system. Please join me in recognizing these outstanding individuals.

That concludes my report to the House of Delegates. I look forward to the next six months as together we build on the accomplishments of these past six. Thank you.

Craig W. Czarsty, M.D.
President

Suicide Is a Private Affair

ROBERT U. MASSEY, M.D.

> I am inclined to follow the course suggested by a friend ... who says that he has always followed the rule never to murder a man who is committing suicide.
>
> —Woodrow Wilson, 1916

BEFORE a record audience last month "Sixty Minutes" showed an insane exhibitionist killing his patient by injecting KC1, an event, I suppose, not surprising in this *fin de siècle* Western world. It was egregiously bad taste, of course, but that hardly matters in these vulgar times. One had only to listen briefly to Dr. Kevorkian to recognize his monomania; according to Dr. Paul McHugh, the Henry Phipps Professor of Psychiatry at Johns Hopkins, he is "'certifiable' in that his passions render him, as the state code specifies, 'dangerous to others.'"[1] If Michigan courts sentence him, they will have created a martyr—exactly what he and the Hemlock crowd want. Good, sound psychotherapy is what he needs, and a monitored retirement.

But the issue will not go away, and the rightness or wrongness of physician-assisted suicide or euthanasia will not be settled by referendum or legislative action or by Mike Wallace's show. Our 18th-century founders, tutored in the Age of Reason, believed in democracy because they believed that the people either had received or had within themselves by virtue of the Natural Law a reliable moral compass, a sound guide in moral philosophy. The fundamental morality of the Judeo-Christian inheritance was thought to be sufficiently binding on all rational creatures to assure mostly decent public as well as private behavior. Transgressions were followed by shame and exclusion, both unpleasant and unprofitable. When support for public morality began to weaken, sins were transformed into laws, and laws could be changed, repealed, disregarded by each new generation. In the process, for many the sense of wrong-doing went by the way, the moral compass became demagnetized, was tossed out, one thing became as good as another, whatever.

> The Americans combine the notions of Christianity and of liberty so intimately in their minds that it is impossible to make them conceive of the one without the other.... in America one of the freest and most enlightened nations in the world fulfills all the outward duties of religion with fervor.[2]

Alexis de Tocqueville wrote that in 1835. We now and will for the foreseeable future live in a postmodern world of moral relativism, multiculturalism, where ideas, texts, ethics, and manners are all of equal value or no value, at least among a highly influential bunch of academics and opinion leaders. "If you believe your idea is true, well, then for you it is!"

This being the case, and we admit to living in a world of moral strangers, where patients must probe their doctors to discover their ethical systems, then we ought to leave the matter of euthanasia or assisted suicide alone. That it is illegal in most places may deter random killing for fear of a whistle-blowing nurse or house officer or suspicious relative. "Mercy" killing will still occur, as it always has, privately where trust between physician and patient has been long standing, and where every precaution has been taken to assure privacy. No need for you or me to approve of that or to disapprove—we'll never know and we are after all moral strangers.

But pass a law making it legal, and it will happen all over the place; not at first, but in 10 or 20 years, at least a third of this voluntary killing will be involuntary, as it is in Holland. The numbers of "lebensunwürtige," those for whom life is deemed not worth living, will grow to include categories of young and old, demented, enfeebled, and deformed, and those who have been subtly persuaded that they are really nuisances, in the way, and awfully expensive.

Finally,we and our representatives should repeat over and over: taking life is never medicine's business. We have sworn that as physicians we will never engage in this kind of morally unsavory practice. Opinions about suicide have differed in the West since ancient times. Cicero: "The god who rules within us forbids us to go hence without his command." Pliny the Elder: "Amid the miseries of our life on earth, suicide is God's best gift to man." How can you settle that by a referendum or in the courts? It is a moral issue, and we physicians can do no better than to hold with our Oath: "I will give no deadly medicine to any one if asked, nor suggest any such counsel."

ROBERT U. MASSEY, M.D., Professor Emeritus, Division of Humanistic Studies, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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MEDICAL NEWS CAPSULES

This Month's Reading in Review

TIMOTHY B. NORBECK

"There has not been a single case that has been filed before this court by an employee coming into federal court saying, 'I want to protect my pension or my benefits under the broad terms of ERISA.' Every single case brought before this Court has involved insurance companies using ERISA as a shield to prevent employees from having the legal redress and remedies they would have had under long-standing state laws existing before the adoption of ERISA. It is indeed an anomaly that an act passed for the security of the employees should be used almost exclusively to defeat their security and leave them without remedies for fraud and over-reaching conduct."

Federal District Court Judge Charles Pickering,
in lamenting his inability to provide relief to a
deserving plaintiff.
Wall Street Journal (27 October 1998)

"In a valedictory address before many of his most loyal supporters," outgoing House Speaker Newt Gingrich (R-GA) explained his decision for leaving Congress, saying he wanted "to spare his party two years of 'divisiveness and factionalism.'" Gingrich used the speech "to lay out a Republican agenda" that includes saving Social Security, cutting taxes, providing school choice, and stepping up the war on drugs.

Washington Post (10 November 1998)

"What surprised me about Newt's speech tonight was ... that he left out the number-one priority of most Americans, and that is to do something about the patient's right to medical care. That was totally missing from the speech and that's by far and away the most popular item on the national agenda.... I think the Republicans are going to have to deal with that, as well."

U.S. News and World Report's David Gergen on
"Larry King Live" (9 November1998)

Aetna—Am I Glad I Met Ya?

Aetna U.S. Healthcare is alleging that Dallas-based Genesis Physicians Practice Association, whose physicians pulled out of Aetna's network in October, is "violating federal antitrust laws by discouraging its membership from returning to the HMO's network under new contracts."... In a letter to Genesis, it claims that the physicians group "improperly and illegally" interfered with Aetna's "attempts to sign new contracts with about" 450 doctors.... The Genesis lawyer downplayed any antitrust considerations, saying, "The doctors are smart enough to know that what we were doing is educational. Antitrust laws don't keep you from educating your members, despite what Aetna's letter may say."

Dallas Morning News (10 November 1998)

Speaking of Aetna, physicians probably are aware of an employee-signed ad campaign in 20 newspapers across the country (2 November) calling for a halt to "unjustified and uninformed attacks on the managed care industry." ... In a recent letter to the editor in response to the Aetna ad, a Connecticut physician said: "Aetna would have better spent the $100,000 it paid for the ads by trimming away some of their administrative layers, authorizing needed treatment for patients or reimbursing the doctors who are owed countless thousands of dollars in unpaid claims."

Hartford Courant (6 November 1998)

Hello! Anybody home?

An online survey conducted by KPMG Peat Marwick LLP finds that 64% of college students surveyed think they will retire by age 50!

Wall Street Journal (3 November, 1998)

"Take charge of your health. In this day of managed care, I can add, if you don't nobody else will.... The right information and the wrong information glows on the computers screen with the same intensity."

Former U.S. Surgeon General C. Everett Koop,
on Internet health information.
San Francisco Chronicle (28 October 1998)

"Congress should resist increasing payments to private plans that operate under Medicare. Instead, we should expect managed-care plans to make good on their claim of providing a more efficient way of delivering quality health care. If they cannot do better than the traditional program, we need to re-evaluate the role they can play in Medicare and certainly should not take further steps to turn Medicare into a system of private insurance plans."

Marilyn Moon, senior fellow and specialist
on Medicare at the Urban Institute.
The Greenwich Time. (18 October 1998)

Only in America: In Mendocino County, California, excon Norman Vroman – whose CV includes twice filing for bankruptcy, owing $1.3 million in tax liens, and strongly supporting the legalization of marijuana, was elected district attorney on November 3!

N.Y. Daily News (5 November 1998)

TIMOTHY B. NORBECK, Executive Director, Connecticut State Medical Society.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgement), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1-1/2 pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent Journal article should be received within six weeks of the article's publication.

In Response to "The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America"

Letter to Dr. Katz: Your article "The Dream That Never Was ..." that appeared in *Connecticut Medicine* (1998; 62:619-20) in October caught my eye. The main point is that I don't like it.

I must confess that I like the single-payer system. You mention that "middle-class people" would not accept entitlements. How did you arrive at that? The Army, the Congress, and the people with executive jobs in industry are all getting and loving entitlements. While we are at it, don't kid yourself that most medical costs are free enterprise (and not government) paid. For today at least 65% are paid for by Uncle Sam. Think of federal money poured into HMOs, medical schools, costs of residencies, research, armed services, and the poor.

You speak as though National Health Insurance is bad. Well, just think that *every* major industrial country from Japan to Sweden have it. They can't be all stupid. All these stories about how the people don't like it are false propaganda. I predict we, in the U.S., will have National Health Insurance within five to 10 years. By the way, while we are at it, at this point you referred to Hillary Clinton, Magaziner, and others as that "ilk." Then you went on to refer to President Bill Clinton as "pretty boy." Now how would you consider my calling you by an unsavory name? After all, in reality, they were doing a great job in helping our country.

I want to have you think. The people pay out money for health insurance. The insurance companies take about 25% for administration and profits. Don't forget the drug companies, the nursing homes, and the "hangers on."

Next come the doctor and the hospitals who are grossly overcharging. Now what is next: all of these are continuing to go up and up in their pricing and the HMOs are raising their premiums. How much longer will the public put up with this? If industry and state and municipal governments were not paying their workers for their medical insurance the uprising would be now.

While I am at it, I'd like to point out that doctors, for the most part, are not participating in a free-enterprise venture but rather a monopoly.

1. Does the patient choose his physician when it comes to an anesthesiologist, a pathologist, or a hospital radiologist?
2. Does a patient have much option when he is in a small town, when there is only one hospital close by?
3. Does he have any control of costs? He cannot bargain with hospitals or doctors.

Lastly—when writing such a paper (as you did) understandably, "you played to the crowd," working on their emotions, making them feel unappreciated and underpaid.

Gregory S. Slater, M.D.
New Britain

Dr. Katz responds: I wish that I had been able to say, as Dr. Slater quotes me, that the middle class would not accept entitlements. If that were so, we would not be contemplating the sorry state of affairs that I wrote about in my article. What I did say, and I fervently believe, is that you cannot socialize a country's medical system until you get the middle class to accept and like entitlements. That is precisely what certain "policy wonks of that ilk" have been working on for the past 30-plus years. And yes, those policies are marketed to the public by politicians with pretty looks and fast talk who sell us the long-standing sub-rosa agendas and creations of others; politicians who comfortably propose the programs of others and aver that they are "free," when they are not!

I also try not to speak of national health insurance programs as being "bad." I merely point out that they are fraudulent. The true costs of such programs are always either hidden, or deferred to future generations, as the Medicare program in this country has already amply demonstrated. Dr. Slater is correct when he says that "every major industrial country from Japan to Sweden has it." Yet despite their draconian rationing of health care and severe underpayment of facilities and practitioners (with significant deterioration of the former), these countries are starting to pay the deferred costs even as we Americans debate the issue as an "idea whose time has come." Thus,

- Japan spent money that it never really had on social programs including national health insurance. Now that country is entering the 10th year of what they are just beginning to acknowledge is a depression.
- Sweden has been in the throws of an economic and monetary crisis for years now, largely because of their "social spending" policies. Although it has not been generally publicized, the Swedish kroner went through a painful devaluation several years ago quite similar to what the Russian ruble is going through

now. Less than two years ago you could earn 50% interest on kroner—if only you were willing to hold them overnight! Furthermore, only now are the Swedes beginning to honestly confront the fallout concerning certain "cost control" aspects of their single payer medical system which included forced sterilization of the poor, the mentally ill, and other "social undesirables." Some of the medical policies under their "National Health Insurance" would have made Nazi Germany proud!

- The Dutch remain hesitant to confront the growing number of statistical studies which show that their use of euthanasia and physician assisted suicide as "cost-effective" measures has often proceeded *without* true "informed consent" of the patient.
- Germany, France, and Italy persist in their social spending policies, including state-controlled National Health Insurance, and they remain mired as well in 12% to 15% chronic unemployment.
- Great Britain, alone among the "social democracies", has begun to recognize the folly of government-ru,n monopolistic social policies. In Britain today, one sign of prestigious employment is employer-paid *private* health insurance. That should tell us something about the "virtues" of National Health Insurance!

Dr. Slater admits that he likes the "single-payer system." Unfortunately, the very term "single payer" is nonsense. The government produces no product and markets no service. In short, the government neither creates wealth nor earns money to pay for the goods and services it uses (or, as it likes us to think, it "gives us"). Government merely confiscates money from taxpayers and redistributes it. *The real payer in "single payer" is all of us.* But the actual costs are hidden from us, and become bloated because of government involvement. I agree with Dr. Slater when he says that if industry, state, and municipal governments were not paying their worker's medical insurance bills, there would be an uprising. *A government's very survival as a "single payer" depends entirely upon concealing from the workers the extravagant overspending by industry and government of what would otherwise be their salaries!* No healthy workers, requiring minimal medical attention most of the time, would ever voluntarily pay the exorbitant amounts for first-dollar insurance that are being secretly removed from their compensation packages! They would quickly demand a catastrophic health program with a large deductible so that they could keep most of their own hard-earned money—and spend it as they wish. And as for the 65% of health care that the government already pays for (according to Dr. Slater), that money has acted much like crop subsidies. It has inflated the costs of goods and services while buying little additional care. Medical costs and spending would be much lower without government meddling. That is an essential truth about government involvement in all markets, throughout all of history.

Finally, I wish that I were "playing to a crowd" that was "unappreciated and underpaid" as Dr. Slater says. If that were so, the hue and cry from physicians would have been so great by now that the policy wonks would never have gotten to where they are in undermining our health care system. But most physicians have remained reasonably comfortable up to now, and therefore they have not forcefully spoken up. As a result, we now stand at the brink of the same abyss of financial ruin to which the "industrial social democracies" have brought themselves with misguided, feel-good policies in health-care delivery. We failed to learn from their disappointing experiences. And so we too will pay a price, through deterioration in the quality and availability of health care for the foreseeable future.

Crowding in noted Swedish hospital may prompt privatization of facility ... Officials are considering privatizing Karolinska Hospital, a longtime symbol of the upside of Sweden's welfare-based health-care system. The hospital, tied to the insitute that awards the Nobel Prize for medicine, is plagued by waits of up to 16 hours for emergency treatment, and doctors are quitting in frustration. It's the same nationwide. In '85, there were 63,000 hospital beds for the coutnry's 8.8 million people; budget cust have cut that to 38,000. *Investor's Business Daily* (30 November 1998, page 2).

Stephen R. Katz, M.D.
President-elect
Fairfield

Need for Solidarity

Letter to the Editor: Dr. Craig Czarsty, the president of the CSMS, made several good points in the October issue.[1] In particular, his comments about the need for physician solidarity warrant re-emphasis. Indeed we have been trained to be autonomous and distrustful of others speaking for us. Though these are good qualities when taking care of patients they are not necessarily so when we need to act in concert for the health of our profession.

We constantly criticize our colleagues who do accept leadership positions yet, surprisingly, many of us balk when asked to serve in leadership positions ourselves. Are we a profession of poor leaders or poor followers? Or little of both? Individualism and independence can be carried to an extreme and for many of us who have accepted leadership positions in the CSMS and in our county medical societies this excess seems rampant.

As Dr. Czarsty said "Physicians will either organize and learn to trust their peers or we will be like most other commodities, easily bought and sold." To some these words may sound pessimistic but to others they may be prophetic. We are proud of our heritage as physicians, of our abilities to work long hours, our dedication, our knowledge, and our valuable contributions to society. But perhaps we have been lulled into complacency, perhaps we have overestimated society's willingness to accord the same respect and protection to us which it readily gave to physicians of earlier generations.

Edward Gibbons in his great work, *The Decline and Fall of the Roman Empire,* emphasized how, in spite of their splendid qualifications as warriors, the Britons gradually lost to the Roman legions. He said that the Britons loved freedom but fought among themselves, and though they were fierce warriors they couldn't organize. Finally they lost out to the discipline and persistent efforts of the Roman soldiers. This is a history physicians could learn something from!

With 24 different medical boards and over 100 different self-designated medical specialties dividing us we have a diffitcult but not insurmountable challenge ahead of us. The early rivalries that managed care instigated between primary care and the specialties no longer exist. Primary care doesn't have any more of a central role in health care now than it did 10 years ago. Some specialists have had their reimbursements cut so drastically that they are having a difficult time maintaining their offices. Colleagues from both sides are increasingly becoming disgruntled and this portends ill both for them and their patients.[2] Some physicians have left active practice to pursue a career in administrative medicine.

The need to speak with a single voice is more necessary now than ever before. At the last house of delegates meeting held in Meriden on 19 November 1998, several concerned members expressed the need for members to collaborate. Now is the time for new ideas, and many physicians are willing to try something that will pull them together. The AMA is experimenting with the idea of having two different categories of membership with different fees.[3] This is a good idea and should be supported.

Personally, I would like to have membership in a specialty society confer automatic membership in the AMA. Perhaps if the specialty societies allocated a portion of members' dues to the AMA? Having most physicians belong to specialty societies and less than half belong to the AMA seems self-defeating for the profession. Specialty societies serve a good purpose; however, it is undeniable that they have also contributed to our fragmentation and rivalries.

I am sure that other physicians also have ideas. I hope that they communicate them to the CSMS and their county medical societies.

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2. Kassirer JP: Doctor discontent. *N Engl J Med* 1998; 339:1534–5.
3. Moran M: Suiting your needs. *AMNews* 16 November 1998 p. 36–8.

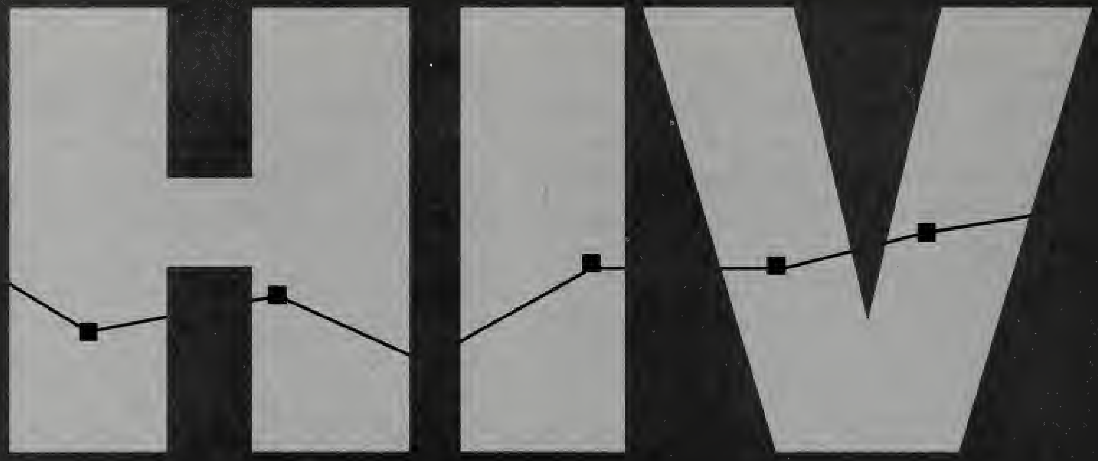
Edward J. Volpintesta, M.D.
Bethel

In Response to Dr. Katz's Commentaries

Letter to the Editor: The excellent commentaries by Dr. S. R. Katz (*Conn Med* 1998; 62:429 and 1998; 62:504) are a wake-up call for the medical profession.

The insidious proliferation (encouraged by insurance companies, HMOs, and the greed of some of our colleagues) of nonphysician clinicians threatens the treaditional practice of medicine. There is one sure way to thwart this attack: Every proposal to permit or increase the scope of practice by these individuals should be met by a proposal that permits paralegals to practice primary legal care.

Samuel Spencer, M.D.
Fairfield



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From the Executive Director's Office

COUNCIL MEETING

Thursday, 15 October 1998

Attendance

In the absence of the chairman, Dr. Hollister, Dr. Deren chaired the meeting. Present, in addition to Dr. Deren, were Drs. Aleali, Beck, Bigos, Bobruff, Conant, C. Czarsty, J. Czarsty, Eslami, Franklin, Geary, Geist, Handelman, Katz, Keating, Lesnik, Maloney, Montegut, Redmond, Sachs, Sadowski, Scarpa, Sosa, Timmerman, Turner, Van Linda, and Wetstone.

Also present were: Mr. Norbeck, Ms. Lindquist, Mr. Brunell, Ms. Morelli, Mr. Staples, Ms. Norbeck, Ms. Schaffman, Mr. Sullivan (all CSMS staff), Mr. A. Schuman, Mr. M. Schuman, (NLCMA, WCMA, MCMA, TCMA Staff), Mr. Coffey, Mr. Fiorentino (HCMA and NHCMA Staff), Dr. Genel (CURE), Dr. Thompson, Mr. Lalime, Dr. Okasha (CSMS-IPA), and Mr. Pepe, (MD Advantage).

Absent were: Drs. Ahamed, Brooks, Carolan, Herzog, Hollister, Narayanan, Schwartz, Sindwani, and Tesoro.

Remarks of the Chair

In the absence of Dr. Hollister, Dr. Deren chaired the meeting. Dr. Deren stated that now that we have the conflict of interest policy, all physicians would be on their honor to recuse themselves from the room if they felt that they have a conflict of interest on the subject being discussed. He also stated that if anyone else felt that someone had a conflict, they should raise the question in a collegial spirit.

Reports of Related Organizations

CSMS-IPA: Mr. Ken Lalime, executive director of the CSMS/IPA, submitted a report which was distributed with the agenda, relating to the ongoing operations of the IPA. It included information that negotiations with senior management of Foundation Health Systems (FHS) have been progressing reasonably well over the past month. In addition to the progress of the negotiations with FHS, the IPA is continuing to review, negotiate, and implement agreements for services for which the IPA is responsible. These agreements are intended to reduce IPA expenses and enhance the IPA financial position. These services include but are not limited to laboratory services agreement with Quest, recontracting for nonphysician services, home care providers, recontracting of hospital outpatient services, and radiology management agreements. It was reported that the IPA has begun identifying a variety of management and monitoring functions that should and will be the responsibility of the IPA. As IPA management reviews those services previously provided to the IPA by FHS, a process of oversight or realignment of responsibilities will be initiated. By creating the IPA infrastructure they can control better their resources in the future. A comparative analysis of IPA financial operations from August 1997 *vs* 1998 was also distributed with the agenda.

Dr. David Thompson addressed the Council and elaborated on the details of the negotiations and the possible ramifications that may result from these negotiations and asked for opinions on the issues being discussed. Following his presentation, there was a lengthy question and answer period. Dr. Deren expressed his appreciation for the reports.

MD Advantage

Dr. Deren gave an overview of MD Advantage stating that it is nearing the close of its first year of operation. He thanked the members of the MD Advantage board for their assistance and stated that they worked very hard on this project. The organization was formed for the sole purpose of serving the physician membership with strategies and services that would help them to cope better with the pressures of managed care. Following are some of the accomplishments: During 1998, MD Advantage provided a regional educational program for physicians considering integration as a managed-care strategy. As a result of that program, a strategic alliance was formed and is the second largest primary care group, allowing over 100 physicians across the state to become part of a one-voice program. The program provides vehicles for physicians to create alliances that result in greater managed-care contracting leverage. MD Advantage developed and secured funding for several regional workshops on providing essential information to physicians. MD Advantage stands ready to provide a vehicle for the execution of the AMAP accreditation program, an initiative which has been previously discussed. While MD Advantage has achieved a number of remarkable accomplishments in its infancy, it was stated that they continue to pledge support of the physician membership in a full slate of quality services that expand with each passing month. MD Advantage will keep the physicians informed of their services through the CSMS ACTION Newsletter.

AMAP

At the 26 August 1998, the CSMS Council voted that CSMS enter into a partnership agreement with the AMA to implement the AMAP program.

Dr. Deren introduced the following resolution from the Board of Directors of MD Advantage, Inc.:

"Resolved, that the CSMS Council authorize MD Advantage, a for-profit affiliate of CSMS, to be the vehicle through which AMAP will be implemented in Connecticut, and that MD Advantage will utilize and contract with AMAP-approved EOC and CVO vendors which agree to meet the national criteria established by AMAP."

Following lengthy discussion, it was VOTED to approve the resolution.

Report of the President

Dr. Craig Czarsty reported that the Ad Hoc Committee he appointed to meet with representatives of the Connecticut Nurses' Association to discuss issues involving the APRN bill was held and that no conclusions were reached. He stated that there probably would not be any compromise on the issue, but that CSMS had made a good faith effort to bring about a compromise.

At the last meeting the president also appointed a Task Force to meet with Dr. Parke, to help him interact with the Department of Public Health on the issue of surgicenter regulations. He asked Dr. Scarpa, who chaired the Task Force, to report on the meeting he had with the members of the Task Force. Dr. Scarpa reported that the Task Force met with representatives of various specialties that would be involved with office surgery, and that may be impacted by restrictive regulations. The Task Force agreed that in-office surgery should not be regulated by licensure or by Certificate of Need. In developing guidelines regarding in-office surgery, the Task Force will utilize those established by other states and national specialty associations. Once the guidelines have been established, they will determine what action to recommend to the Council.

Dr. Craig Czarsty reported that he attended the semiannual meeting of the Fairfield County Medical Association and the HCFA administrator was the guest speaker. At the end of her presentation, she invited private physician participation with HCFA in looking at E&M codes, and would welcome physicians to come down to Baltimore and spend some time with them. He reported that he wrote a letter to HCFA suggesting that they invite Dr. Edward Kamens who may be able to give the physicians' point of view on E&M coding.

Report of the Executive Director

Mr. Norbeck reported on the following items:

It was reported that managed-care reform was dead at the federal level; interparty struggles have undermined any chance to see patient protection legislation enacted. In a 50-47 vote, the Senate turned down an effort to bring HMO legislation to the floor. Such reforms are hot political issues in gubernatorial races in Florida, Arizona, Ohio, and in the Senate races in Kentucky and North Carolina, and in dozens of House contests.

A federal judge in Houston upheld a Texas law that holds HMOs liable for denying medically necessary care. Judge Vanessa Gillmore ruled that the new Texas law is not preempted by ERISA, as suggested by HMOs and the insurance industry. The Texas law allows patients to sue employer-sponsored health plans and health insurers when the plan's decisions result in injury, death, or economic loss. It went into effect in September 1997, but was immediately challenged by Aetna. The ruling should open the door for similar legislation in other states

In the latest report from the Taubman Center for State and Local Government at Howard's JFK School of Government, Connecticut ranked No. 1 in a very dubious awards list of states whose taxpayers paid more in federal taxes for 1997 than they received back in federal spending. New Jersey, which led this list in 1996, took second place. New Mexico again topped the list of "surplus" states that received more in percapita federal outlays than they paid in federal taxes. North Dakota was second.

Mr. Norbeck also reviewed some of the political races taking place throughout the country.

Meeting of Maine Medical Association

Dr. Anthony Redmond, delegate to the Maine Medical Association, submitted a written report outlining the actions of the Maine House of Delegates. He reported that their number one concern was the confidentiality of health-care information and successfully passed a comprehensive bill which states that health-care information is confidential. The theme of the House was to identify what the medical association could do to help its constituents, and priority should be given to listening and learning from the members of the Association and then to attempt to satisfy their needs. It was VOTED to receive the report as information.

Report of Connecticut Medical Insurance Company (CMIC)

Dr. Sultan Ahamed, president and chairman of the Board of CMIC, was unable to attend the meeting and submitted a written report. The highlights of the report were as follows:

A.M. Best rating of A. (Excellent) reaffirmed.

Membership remains over 3,100.

Retention rate at 98%.

Rates remain unchanged for 1999 policy year.

Policyholder dividend for 1999 tops $6 million with policy repayments reaching 26.9 million.

Former CNA-insured physicians make smooth transition to CMIC.

It was VOTED to receive the report as information

Dates of Future Meetings

Council Meeting—Wednesday, 20 January 1999

Annual Meeting—House of Delegates,
Wednesday, 12 May 1999

Semi-Annual Meeting—House of Delegates,
Wednesday, 17 November 1999

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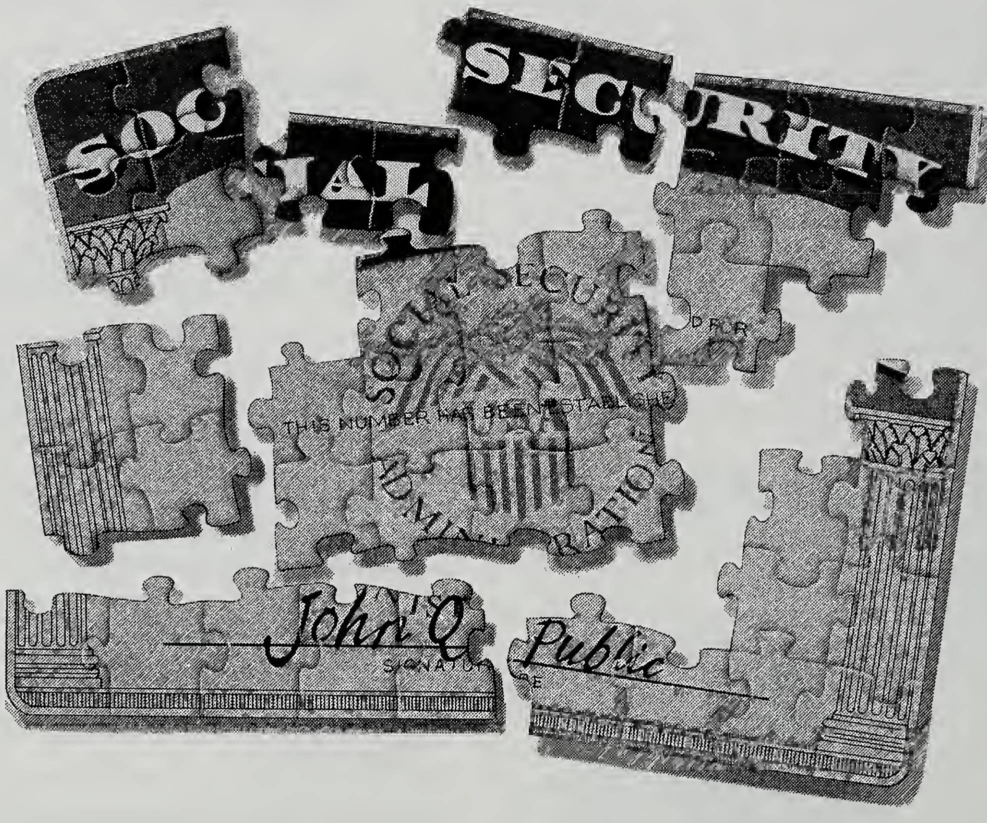
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SUMMARY OF PROCEEDINGS
CSMS HOUSE OF DELEGATES — SEMI-ANNUAL MEETING
RAMADA INN, MERIDEN—19 NOVEMBER 1998

Reports and Addresses

The House received reports, addresses and/or remarks from the president, the Council, the AMA Delegation, the executive director, Connecticut Medical Political Action Committee (COMPAC), Connecticut Medical Insurance Company (CMIC), and CSMS-IPA. Most of the reports were published in the Handbook previously distributed to the delegates. The reports of the President Dr. Craig Czarsty and the Executive Director Tim Norbeck appear elsewhere in this Journal. Dr. Percy Wootton Immediate Past President of the AMA addressed the House.

Special Awards

David Parke, chair of the CSMS Legislative Committee, introduced to the House Representative Anne McDonald, house chair of the Public Health Committee, who was presented with the CSMS Legislative Award of Excellence and Commissioner Stephen Harriman, commissioner of public health, who was presented with the CSMS Leadership Award.

Principal Actions Taken

(a) ***Report of the President,*** Craig Czarsty, M.D., Oakville, Dr. Czarsty's report to the House appears as the President's Page in this issue of *Connecticut Medicine.* The report was received as information.

(b) ***Report of the Council,*** Dickerman Hollister, Jr., M.D., Greenwich, chair. The House voted to accept, as information, the report of the chairman of the Council, which reviewed the activities of the Council since the last meeting of the House of Delegates. Minutes of the interim Council meetings have already been published in *Connecticut Medicine.* Special emphasis was given to the reports from related organizations such as M.D. Advantage, CSMS-IPA, the various reports given at each meeting by the president, the executive director, and the chairman of the committee on legislation. The Council also submitted a budget for 1999 and the action taken on the Council's recommendation appears elsewhere in this summary. The Council reported its approval of the following resolution concerning the American Medical Accreditation Program (AMAP);

RESOLVED, that the CSMS Council authorize M.D. Advantage, a for-profit affiliate of CSMS, to be the vehicle through which AMAP will be implemented in Connecticut, and that M.D. Advantage will utilize and contract with AMAP-approved Environment of Care (EOC) and Credentials Verification Organization (CVO) vendors which agree to meet the national criteria established by AMAP.

Two items were submitted to the Council by the Committee on Ethical and Judicial Affairs on the subject of conflict of interest. The Council approved the following items:

Proposal Regarding Disclosure of Conflict of Interest.—"All persons nominated for positions as Officers and committee chairpersons of the Connecticut State Medical Society shall disclose for publication in the Delegates Handbook, prior to the election any and all business relationships with insurance and managed-care entities, other than the usual "third party" practice relationships. Additionally, this information shall be published annually in *Connecticut Medicine* together with the same information for all members of the CSMS Council as well as senior management of CSMS."

Conflict of Interest Policy.—The Council approved a seven-page report, which has been published in the October 1998 issue of *Connecticut Medicine.*

The report of the Council was received as information.

(c) ***Report of AMA Delegation,*** Joseph S. Sadowski, M.D., Hartford. The House voted to accept the report of the AMA Delegation as information

Medicare documentation guidelines, collective bargaining for physicians, and the first debate between candidates for president-elect stood out among the issues discussed at the annual meeting. Delegates voted to oppose "any documentation system that requires quantitative formulas or assigns numeric values to elements in the medical record." In other issues, the House:

- Directed AMA and state societies to oppose expansion of the scope of practice of nonphysician health care providers.
- The House reaffirmed its support for overturning federal laws that protect managed-care organizations from liability for negligent medical decisions that

harm patients. Delegates also stated that medical directors of managed-care organizations should be subject to state medical licensing requirements, medical board review, and disciplinary action.

- Made no change in the AMA dues structure for 1999.
- Did not adopt a controversial report from the Council on Ethical and Judicial Affairs that would have deemed it unethical for physicians to sell nonprescription health products from their office at a profit.
- Relative to Medicare payment policies, the House voted to oppose strongly the imposition of any "user fees, provider taxes" on participating physicians. Delegates directed the AMA to "take specific legal action" unless HCFA rescinds within 90 days its recent decision to slow down payment of Medicare claims.

Nancy W. Dickey, M.D., was installed at the meeting as AMA's first woman president. Thomas R. Reardon, M.D. was elected as president-elect of the AMA.

(d) ***Executive Director,*** Mr. Timothy B. Norbeck, New Haven. The House voted to accept the report of the executive director, as information, which appears in its entirety at the conclusion of this summary.

(e) ***Connecticut Medical Political Action Committee (COMPAC).*** Donald D. Timmerman, M.D., Glastonbury, chair of the Connecticut Medical Political Action Committee, gave an update on the current status of COMPAC. He reported that physician support over the past two years enabled COMPAC to become a visible supporter in a majority of the state campaign races this year. He congratulated the Connecticut Society of Eye Physicians for taking the lead this year and hosting several fundraisers for key members of the State Legislature. Several physicians around the state took the initiative and hosted or attended candidate fundraisers, proving that the M.D. can make a difference.

He noted that at the COMPAC annual meeting it was being proposed that the COMPAC change its name to an acronym that is more identifiable with physicians, such as Medical Doctors Political Action Committee (M.D.PAC) (Note: at the annual meeting, the name change was approved.)

The report was received as information.

(f) ***Report on Connecticut Medical Insurance Company, (CMIC).*** Sultan Ahamed, M.D., president and chairman of the Board of Connecticut Medical Insurance Company (CMIC) reported the following:

- Current rates will remain unchanged until the year 2000. The cost to the policyholders will be further reduced through the distribution of the $6 million policy holder dividend. The eighth consecutive dividend is an increase of $2.5 million above the 1997 dividend.
- CMIC's average premium, before policyholder dividends has declined over 15% since 1995, continuing their commitment to provide the best insurance product available with competitive premiums.
- Membership remains over 3,100 with a retention rate of 98%.

The report was received as information.

(g) ***Report on CSMS-IPA:*** Mr. Ken Lalime, executive director of the CSMS/IPA, reported on the ongoing operations of the IPA. His report included information that negotiations with senior management of Foundation Health Systems (FHS) have been progressing reasonably well. In addition to the progress of the negotiations with FHS, the IPA is continuing to review, negotiate, and implement agreements for services for which the IPA is responsible. These agreements are intended to reduce IPA expenses and enhance the IPA financial position. These services include but are not limited to laboratory services agreement with Quest, recontracting for nonphysician services, home care providers, recontracting of hospital outpatient services, and radiology management agreements. It was reported that the IPA has begun identifying a variety of management and monitoring functions that should and will be the responsibility of the IPA. As IPA management reviews those services previously provided to creating the IPA infrastructure they can better control their resources in the future. Dr. David Thompson, president of the CSMS/IPA, addressed the House on CSMS/IPA issues. A list of the CSMS/IPA Board of Directors was included with the report.

The report was received as information.

(h) ***1999 Budgets:*** The House voted to approve the operational budget, a capital budget, and a Physician Health and Education Fund Budget. The dues will remain at $390.

(i) ***New Business:*** Eight resolutions were introduced and were acted on as follows:

Resolution:
Coverage of Medication Delivery Devices

Introduced by Fairfield County Medical Association and adopted with amendments as follows:

RESOLVED, that CSMS seek legislation that any device required for the administration of a prescribed medication be covered and paid for by the insurance company.

Resolution:
Reaffirmation of the "Fairness for Patients" Policy

Introduced by the Fairfield County Medical Association and adopted with amendments as follows:

RESOLVED, that to assure continuity of care and preservation of the patient-physician relationship, CSMS shall again actively seek legislation which requires HMOs to accept all licensed physicians who agree to abide by the health plan's policies and procedures.

Resolution:
Diminish the Inadequacies of our Current Malpractice System

Introduced by Fairfield County and the following substitute resolution was adopted:

RESOLVED, that CSMS Council shall study HMO liability, State Department of Public Health postclosure investigations, malpractice tort reform, and alternative dispute resolution, and report back to the next House of Delegates.

Resolution:
Study New Ways Connecticut's Physicians Can Play a Greater Leadership Role in Health-care Reform

Introduced by Edward Volpintesta, M.D., delegate from Fairfield County, and was accepted for information and not adopted.

Resolution:
HMOs Medical Liability

Introduced by Edward Volpintesta, M.D., delegate from Fairfield County and the following action was taken: The resolution was not adopted since it was incorporated with a previous resolution entitled "Diminish the Inadequacies of Our Current Malpractice System."

Resolution:
Promotion of Solidarity Among Physicians

Introduced by Catherine S. Hair, M.D, delegate from Fairfield County Medical Association.

Resolution:
Specialty Society Representation in House of Delegates

Introduced by New Haven County Medical Association.

Neither of these resolutions were adopted and the House voted to refer them to the Council for study and for engaging the specialty societies in greater collaboration, such as a periodic Council of Presidents.

Resolution:
HIV Infection

Introduced by Litchfield County Medical Association

This resolution did not appear in the handbook, and it was not adopted.

Awards
CSMS Past Service Awards to County Councilors

Fairfield County

Francis J. Scarpa, M.D., Greenwich, Associate Councilor and Councilor, 1993–1998

Stephen R. Katz, M.D., Fairfield, Associate Councilor, 1994–1998

New Haven County

Ellen R. Fischbein, M.D., Cheshire, Associate Councilor, 1996–1998

Steven Wolfson, M. D., New Haven, Associate Councilor and Councilor, 1990–1998

Middlesex County

Donald D. Timmerman, M.D., Portland, Associate Councilor and Councilor, 1992–1998

New London County

Joseph P. Zeppieri, M.D., Groton, Associate Councilor, 1995–1998

Windham County

James E. Watson, M.D, Mansfield, Councilor, 1994–1998

Lee S. Wesler, M.D., Dayville, Associate Councilor, 1996–1998

COMMITTEE SERVICE QUESTIONNAIRE

Connecticut State Medical Society

Early in 1999 the Councilors from the eight constituent county medical associations will assume the responsibility of selecting members of the Society to participate in the various activities of the Society, listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

Executive Director's Office
160 St. Ronan Street
New Haven, CT 06511

Your cooperation will be appreciated.

Medical Education

- ★ Committee on Continuing Medical Education

Medical Economics

- ★ Committee on Insurance
- ★ Committee on Workers' Compensation
- ★ Managed Care Patient Advocacy Committee

Professional Relations

- ★ Committee on Ethical and Judicial Affairs

Public Affairs and Communication

- ★ Editorial Committee on *Connecticut Medicine*
- ★ Committee on Legislation
- ★ Committee on Public Affairs

Scientific and Socio-environmental Medicine

- ★ Cancer Coordinating Committee
- ★ Committee on Physician Health
- ★ Committee on Maternal Morbidity and Mortality
- ★ Committee on Medical Aspects of Sports
- ★ Committee on Organ and Tissue Transfers
- ★ Committee to Study Perinatal Morbidity and Mortality
- ★ Committee on Public Health
- ★ Committee on Geriatrics
- ★ Committee on Medicare
- ★ Committee on Allied Health Services
- ★ Committee on Alcohol and Other Drug Dependency Education

Representative and Advisors

- ★ Representatives to Connecticut Advisory Council on School Health
- ★ Delegates to Connecticut Public Health Association, Inc.
- ★ Delegates to Connecticut Nutrition Council

Please return by January 15, 1999

Name:____________________________________ M.D.
(Please Print)

Office Address: ____________________________________

____

Address of the Executive Directive

CSMS House of Delegates—Annual Meeting

19 November 1998

TIMOTHY B. NORBECK

SINCE its founding 111 years ago in 1887, the *Wall Street Journal* has refused to endorse political candidates. The lone exception occurred 70 years ago in 1928 when the journal supported Herbert Hoover. "Never again," vowed the editors, for they realized, as their founder Charles Dow proclaimed: that "Politicians, properly observed, often will disappoint—ideas, properly understood, seldom will." The *Journal* caught on to this about the same time as Will Rogers did.

One hundred ninety-eight years ago Tuesday, the U.S. Congress met for the very first time. And its reputation for prolonged debate continues to this day. As Will Rogers said: "Congress is the only place where someone gets up to speak, says absolutely nothing, no one listens—and after a few minutes, they all disagree."

Everyone learned that lesson this year, where despite a groundswell of support for patient protection legislation at the federal level, the bill languished in Congress and died. There were reasons, of course, why it failed and time doesn't permit me to go into them now—but suffice it to say: They can run; but they can't hide. A pessimist claims that an optimist is someone who hasn't heard the news. Trust me, I am an optimist who has heard the news, and patient protection legislation will be back next year and it will pass.

The year of 1999 will be the year of regulatory pay back for managed care organizations. Speaking of pay back, I am reminded of the married couple who had been in a terrible accident where the woman's face was severely burned. The doctor told the husband that they couldn't graft any skin from her body because she was too thin. So the husband offered to donate some of his own. However, the only skin on his body that the doctor felt was suitable would have to come from his buttocks. The husband and wife agreed that they would tell no one about where the skin came from, and requested that the doctor also honor their secret. After all, this was a delicate matter. After the surgery was completed, everyone was astounded at the woman's new beauty. She looked more beautiful than she ever had before! All her friends and relatives just went on and on about her youthful good looks! One day she was alone with her husband, and she was overcome with emotion at his sacrifice. She said, "Dear, I just want to thank you for everything you did for me. There is no way I could every repay you." "My darling," he replied, "think nothing of it. I get all the thanks I need every time I see your mother kiss you on the cheek."

"You cannot get a judgment against a doctor," declared a *Medical Economics* article in 1934. Malpractice insurance was something doctors carried, but assumed they wouldn't need. In fact, most doctors those days had never even heard of a malpractice lawsuit within their own professional circle. How things have changed.

Only physicians and their families truly know the emotional heartbreak and toll taken on their lives by an unjustified malpractice suit. In 1986, a Long Island physician was served with such a suit. His patient had presented with chest pains and was advised to go directly to the hospital. The man refused, saying he had a bridge game. After having a heart attack, he sued, claiming the doctor had failed to diagnose and treat his heart condition. The patient survived, but the doctor committed suicide. I'm proud to say that our own CMIC has pioneered a program that helps our physicians and their families to maintain their perspective when legally attacked, and to cope with the painful disruptions.

The election 16 days ago had both good news and bad news for medicine. The good news is that five more

Democrats are coming to the U.S. House of Representatives in January—Remember: The "Patients' Bill of Rights" lost by only those five votes in congress this fall. As for the bad news, the Republicans were hoping to win five more seats in the Senate so they would have had a filibuster-proof majority of 60 U.S. Senators, but failed to gain any. Had that come to pass, significant tort reform would have been likely. The trial lawyers are breathing a lot easier today than they were 17 days ago, but we must not lose heart—and we must continue our efforts.

Speaking of our lawyer friends, I am reminded of a story about a fellow who was stuck in a traffic jam that hadn't moved for more than half an hour.

Looking out his car window, he saw a kid on a skateboard weaving his way towards him through the line of stranded vehicles.

"Hey son, what's the holdup?" the man asked.

"It's some crazy lawyer," replied the kid, "he's lying in the middle of the road and he's doused himself with petrol and is threatening to set himself on fire. We're taking up a collection for him. Would you like to donate, mister?"

"How much have you got so far?" the fellow inquired.

"Oh," said the kid, "about 30 books of matches and 23 lighters."

While I am on the subject of lawyers, there is another story circulating that St. Peter is trying to establish new guidelines for admission to Heaven so that the unworthy do not slip through the gates. The questions being asked by St. Peter are much tougher for those deemed unfit to enter.

Recently a teacher, a tobacco lobbyist, and a lawyer wound up together at the Pearly Gates. St. Peter informed them that in order to get into Heaven, they would each have to answer one question.

St. Peter addressed the teacher first and asked, "What was the name of the ship that crashed into an iceberg? They just made a movie about it." The teacher answered quickly, "That would be the Titanic." St. Peter let him through the gate.

St. Peter then turned to the tobacco lobbyist and, figuring Heaven didn't really need this guy, he decided to make the question a little harder: "How many people died on the ship?" Fortunately for him, the lobbyist had just seen the movie and answered, "about 1,500." "That's right! You may enter."

Finally St. Peter turned to the lawyer, and said: "Your question is, what were their names?"

Another terribly oppressive problem faced by physicians in Connecticut as well as throughout the country is, of course, the matter of delayed and late payments from health plans. Thanks to a super effort by your Connecticut State Medical Society and the county medical associations working together effectively, and with thanks to our hard-working, dedicated, and courageous state legislators who stood up to the might of a hostile and belligerent insurance industry lobby, help is on the way.

Effective 1 January 1999—43 days from now, insurers will pay 15% interest for claims not paid within 45 days, but even more importantly, late or delayed payment of claims owed physicians becomes an "unfair insurance practice," giving power of enforcement to the Attorney General and the Insurance Department.

But the HMOs continue to shoot themselves in the foot.

Even Lynn Etheredge, a leading member of the Jackson Hole Group which conceived modern-day managed care, was quoted last month as saying that: "The future of the managed-care industry depends on public trust and confidence, and the industry has blown that. It's not just patients' horror stories that have eroded public confidence. Skimpy benefits are only part of the problem. The larger problem is that no one knows how well different plans are performing."

The Congress-inspired movement to lead millions of our elderly into Medicare HMOs is now looking like a very tenuous solution at best. Hundreds of thousands of Medicare patients are being abandoned by their HMOs, including thousands in our state. I wouldn't lay all the blame at the feet of HMOs, because we all know what the deleterious effect of deep Medicare cuts has been on physicians and others in the program. And HCFA bears some responsibility in this snafu too, as their reporting requirements and timing were faulty. But it does seem to me that HMOs are culpable, too, for their eager and aggressive campaigns to enroll Medicare patients with as much haste as possible. This unfortunate situation, tragic for some seniors, will boomerang on the managed-care industry and force more Republicans in Congress, heretofore its greatest champions, into supporting national patients' rights legislation in 1999—unless they want to risk the wrath of senior citizens and other voters any more than they already have.

"Can't fool around with ERISA," is always the chant of those who do not wish to make HMOs accountable. If that argument doesn't resonate, then they resort to the old, over-worked and proven effective sound bite that "it costs too much and there will be too many suits." Now along comes a timely Coopers & Lybrand study conducted for the Kaiser Family Foundation which basically says that this argument is baloney. Based on the experiences of public programs in California and Colorado, which have long given enrollees that right, the right to sue will cost no more than pennies per member per month.

What could be more relevant to the abuse of the ERISA shield than comments made by Federal District Court Judge, Charles Pickering.

Lamenting his inability to provide relief to a deserving plaintiff, he wrote: "There has not been a single case that has been filed before this court by an employee coming into federal court saying, ' I want to protect my pension or my benefits under the broad terms of ERISA.' Every single case brought before this Court has involved insurance companies using ERISA as a shield to prevent employees from having the legal redress and remedies they would have had under long-standing state laws existing before the adoption of ERISA. It is indeed an anomaly that an act passed for the security of the employees should be used almost exclusively to defeat their security and leave them without remedies for fraud and over-reaching conduct."

But this year, things are finally starting to change. Texas passed a law to allow patients to sue HMOs, Aetna challenged it, and subsequently lost on appeal. There will be others. And one more thing. That old "too-many suits" would result from such legislation argument is another phony sound-bite coming from opponents of accountability. A suit against an HMO just filed in Texas on 19 October 1998, interestingly was the first one filed since the legislation was enacted in May of 1997.

And look what happened in Connecticut just 24 days ago. In a huge decision, U.S. District Court Judge Christopher Droney ruled in a Danbury case that HMOs can be sued for medical negligence—a ruling which is certain to fan the nationwide flames calling for more HMO accountability to their patients. Ah, at last, the hassle factor works both ways.

Yes, indeed, the tide is turning. If there is one irrefutable lesson to be learned from history, it is that excesses inevitably are their own undoing. Wall Street, the altar at which most for-profit health plans worship, is losing faith in the managed-care industry's ability to manage costs—let alone patient care. As *Modern Healthcare* points out, even employers are questioning the huge chunk of health-care premiums being gobbled up by managed-care companies for administrative expenses.

In a new book, well-respected medical economist J.D. Kleinke, argues that managed care in its current form is unsustainable and will "cease to exist within a few years. —Physicians," he says, "have an intellectual incumbency that will reign in the end, which stands in sharp relief to the naked ambitions and hollow advertising of MCO marketers." Regulation is coming and if it does mean, as the nay sayers predict, that managed care will be less profitable, so be it. Perhaps it will serve to drive out those entities and individuals who got into the industry only to make a killing—the people who are there for the wrong reasons.

Like the young lawyer who was in a swank Beverly Hills restaurant and spotted the billionaire oil man, J. Paul Getty.

The lawyer went over to his table and very humbly said, "Mr. Getty, please forgive me for interrupting your lunch, but please, Mr. Getty, I'm expecting two of my best clients to come in and I would be forever grateful if sometime during our lunch, you would stop by my table and say, 'Hello Bernie.' You don't know what it would mean to me." The lawyer then returned to his table, where his clients joined him. Getty and his guest had finished and were on their way out of the restaurant when Getty suddenly remembered the young lawyer's request. He went back to the lawyer's table and, tapping him on the shoulder, said "Hello, Bernie." Angrily, the lawyer replied, "Not now, Getty, I'm eating."

Employers do show signs of understanding the problem. Consultants Booz Allen and Hamilton says as many as 60% of very large companies are mulling a shift to defined contribution health benefits—something the AMA is fighting for and believes will give patients a real choice. As *Business Week* puts it, "Consumers don't like HMOs. No matter that HMOs' care appears to be as medically sound as any other. Americans are far more likely to trust their physicians than they are the insurer, which is often perceived as meddling needlessly."

There is an old African proverb that says if there is no enemy within, the enemy outside can do us no harm. The tide is turning and physicians must be in position and ready to capitalize on it. Nobody can beat us but ourselves. Physicians must stand together. There is no shortage, of course, of doomsayers who would point to a bleak future for medicine. I don't believe it, and you shouldn't either. Unfortunately, progress seems to come by the inch, but we are moving forward. Look where we were with the state legislature just two and one-half years ago when any kind of managed-care reform was dead on arrival. Now Connecticut is a leader among the states in such legislation, and has sparked the demand for national action.

In closing, your patients trust you with their lives and they trust you to be their advocates. There is no more precious gift than that of good health, and that is what you and your colleagues deliver. The public already knows where the priorities of predator health plans lie, but people must never be able to doubt that your number one priority begins and ends with your patients—no matter what!

So physicians must not give up the fight. There is too much at stake. Your patients—your profession—the nation's good health. You must believe in yourselves as never before. We do have plenty of problems to solve for patients and for physicians, but if not us, who else is going to do it? The government? The news media? Wall Street? Employers? I don't think so.

Perhaps it was best put by the late musical artist from the Grateful Dead, Jerry Garcia, "Somebody has to do something, and it's just incredibly pathetic that it has to be us."

Need ISBN number and price of book

BOOK REVIEW

Letters and Journal of a Civil War Surgeon
By Stewart J. Petrie, M.D.
ISBN 1571970959, 166 pp., Raleigh, North Carolina.
Pentland Press, 1998. $21.95

Dr. Myron W. Robinson (1839–1912) was a surgeon with the 6th Connecticut Volunteers for the duration of the Civil War. His great grandson, Dr. Stewart J. Petrie, has used his letters and journal to recreate Dr. Robinson's wartime experience with the Union Army in America's deadliest war.

Myron Robinson, a native of Hebron, Connecticut, received his formal medical education at the Berkshire Medical School in Pittsfield, Massachusetts, from 1858 to 1860, the usual two-year period. As was customary at the time, Dr. Robinson's medical education consisted of a series of lectures that were simply repeated in the second year. According to Kenneth Ludmerer in his book, *Learning to Heal: The Development of American Medical Education,* "Students endured six to eight hours of lectures daily.... The inevitable result of the system: 'physical and mental dyspepsia.'"

He served a preceptorship with a Dr. Craig who was a practitioner in his home town. Dr. Robinson saw the advent of the Civil War as a professional opportunity to develop clinical experience and to secure a financially stable government position. He decided, therefore, to enlist in the U.S. Army as a doctor.

Dr. Robinson's military orders placed him primarily in three locations: the islands near Fort Sumter, South Carolina; Fort McHenry, Baltimore; and, finally, in trench warfare on the Richmond/Petersburg line in Virginia. He was the medical corps responsible for the sick and wounded during the battle for Fort Wagner, a battle which, incidentally, was the basis for the film *Glory*. It was during this battle that the Negro infantry distinguished itself under the leadership of Colonial Robert G. Shaw. The intensity and character of Dr. Robinson's work with the wounded in this fire fight is emblematic of the picture of Civil War medical care that emerges from his journal and letters.

The two major limitations in Civil War combat medicine graphically brought out through Dr. Robinson's writings are the almost universal resort to amputation for bullet-inflicted compound fractures to the extremities, and the often ineffective efforts to maintain the health of the troops in the absence of an understanding of the bacterial cause of diseases among soldiers living in battlefield conditions. This latter factor resulted in more deaths from disease than from battle wounds and injuries. Of the 360,000 Union deaths from all causes, 200,000 were from disease while 110,000 were killed outright or mortally wounded in battle.[1]

A quotation from this book captures these two limitions: "We knew even then that amputations were done too readily, but often the alternatives were worse. They would would suppurate and infection would spread. A late amputation was fraught with the dangers of suppurating wounds followed by fever and death; it seemed that this suppuration was easily transmitted to newer cases that we operated on."[2(p.19)]

Chloroform and ether were used as anesthetics during amputation. Robinson notes that during the attack on Fort Wagner supplies of chloroform began to run low before resupply was furnished. However, he describes no cases of amputations performed without the use of either chloroform or ether. Concern for the flammability of ether required that lanterns be kept away from operating tables during night-time surgery increasing the difficulties in what was, by modern standards, a relatively primitive procedure.

Experience had demonstrated the health effectiveness of locating latrines away from drinking water and hospital tents. The work of Louis Pasteur and Robert Koch on microorganisms as the cause for disease was yet several years away. The Confederate experience with boiled horsehair as suturing material puts the empirical basis for what really was a form of antibacterial practice into perspective. A medical observation was made regarding the excellent wound healing of some rebel prisoners. There was little or not redness, infection, or induration around the sutures closing of lacerations. By questioning these troops, it was learned that in the absence of regular suture material, horsehair was used. Horsehair being quite stiff, it was boiled in water first, effectively sterilizing it, with good results for the wound healing.[3(p.21)]

By many accounts of medical and surgical care in the Civil War, medicine is here realistically portrayed as quite incapable of responding even in a minimally adequate manner to the industrialization of killing represented by mass armies with rifled gun barrels, canons, and torpedoes given the instruments, techniques, and concepts available at the time.

Petrie has organized the text so that Dr. Robinson's letters are printed in italics preceded and followed by first person narrative that apprears as his journal. To provide a broader historial perspective, Petrie has included historical notes and contemporary first person accounts of Civil War events that coincide with those in which his great grandfather participated. The reader follows Dr. Robinson from his medical school days through his post-war practice as a local physician in Colchester, and finally as the superintendent of the Fitch Soldiers' Home in Noroton, Connecticut.

There are many details to interest a historian of American medicine. Clara Barton and her nursing services are mentioned in conjunction with the South Carolina battles. John Shaw Billings, later to be the founder of what is now the National Library of Medicine, is cited in his role of medical equipment quartermaster. Dr. Robinson notes Billings' order to account carefully for all material he has received from the War Department.

After the war, Dr. Robinson entered a residency program at Bellevue Hospital in New York. He observed that the use of the stethoscope was now becoming common, even though that diagnostic tool had been introduced by René Laennec in France in 1820. Apparently it took almost a half century before this useful clinical instrument became common in the United States.

To hold this book to academic standards would be unfair as the author intended it to be simply the publication of the account of an army surgeon's travails and experiences during the Civil War. Consequently, although footnotes and an index would have increased the work's usefulness as a contribution to medical history, these features were not part of Dr. Petrie's intention. Dr. Petrie has elaborated on Dr. Robinson's journal and the journal portion of the text is interpolated with background material, descriptive writing on generic topics such as heat, insects, and ocean sand!

Dr. Petrie has, in short, made accessible primary research material on Civil War medicine. Although *Letters and Jouranl of a Civil War Surgeon* is not intended as a scholarly treatise, it does add to the literature of the Civil War from one who was really there, the comments of an eyewitness whose steadfast commitment to duty, battle-induced depressions, and repeated requests for more letters from home ground Dr. Robinson's writing in a reality that transcends time.

REFERENCES

1. Paul E. Steinner. *Disease in the Civil War.* Springfield, Mass: Charles C. Thomas, Publisher, 1968. p. 8.
2. Petrie SJ: *Letters and Jounals of a Civil War Surgeon.*

Ralph D. Arcari, Ph.D.
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Assistant Vice Chancellor for Academic Resources and Services and Director,
Lyman Maynard Stowe Library,
University of Connecticut Health Center

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IN MEMORIAM

ADAMS, HENRY A., School of Physicians, Trinity College, University of Dublin, Ireland 1947. Dr. Adams was a general practitioner in Cromwell for over 30 years, retiring in 1994. He was associated with Middlesex Hospital in Middletown. Dr. Adams was a member of the Middlesex County Medical Association and the Connecticut State Medical Society. Dr. Adams died 21 November 1998 at the age of 84.

CUTLER, HERMANN S., St. Louis University School of Medicine, 1937. Dr. Cutler, a pulmonologist, established the Chapel Medical Group. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Cutler died 4 November 1998 at the age of 88.

EMMEL, ROBERT C., Cornell University Medical College, 1945. Dr. Emmel maintained a private practice in obstetrics and gynecology in West Hartford for 36 years and was on the staff of Hartford Hospital, retiring in 1990. He was an assistant clinical professor at the University of Connecticut School of Medicine. Dr. Emmel was a member of the Hartford County Medical Association and the Connecticut State Medical Society where he served on the committee to study perinatal morbidity and mortality from 1966 to 1978. Dr. Emmel died 1 October 1998 at the age of 78.

GEANURACOS, GEORGE J., State University of New York College of Medicine, Brooklyn, 1944. Dr. Geanuracos practiced obstetrics and gynecology at Bridgeport Hospital where he was a member of the staff executive committee, the accreditation and bylaws committee, and chaired the medical staff evaluation committee. He instructed nurses, interns, and residents at Bridgeport Hospital and St. Vincent's Hospital. Dr. Geanuracos was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Geanuracos died 16 November 1998 at the age of 78.

GOTTLIEB, FELIX, John Hopkins University School of Medicine, 1962. Dr. Gottlieb, a psychiatrist, was a captain in the United States Public Health Service and a former director of the Drug and Alcohol Rehabilitation Program at Bridgeport Mental Health Center. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Gottlieb died 15 November 1998 at the age of 62.

KREIS, DAVID J. SR., Tufts University School of Medicine, 1947. Prior to his retirement in 1996, Dr. Kreis practiced obstetrics and gynecology with the Greater New Haven Obstetrics and Gynecology Group, P.C. and was an associate clinical professor of obstetrics and gynecology at Yale University. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. Kreis died 23 October 1998 at the age of 76.

LOBB, RUSSELL A., Hahnemann Medical College and Hospital, 1937. Dr. Lobb began his general practice of medicine in Deep River in 1938 and remained there until his retirement in 1987. He served as assistant medical examiner for 35 years. Dr. Lobb was a member of the Middlesex County Medical Association and the Connecticut State Medical Society where he served on the Liason Committee for the State Department of Income Maintenance for 10 years. Dr. Lobb died 23 November 1998 at the age of 89.

McINTYRE, FREDERICK P., University of Vermont College of Medicine, 1942. Dr. McIntyre practiced medicine in Stamford until his retirement in 1986. He served on the attending medical staff at Stamford Hospital and St. Joseph's Hospital. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association. Dr. McIntyre died 12 November 1998 at the age of 83.

McSHANE, KATHLEEN J., Pennsylvania State University College of Medicine, 1976. Dr. McShane was the founder and one of the principals of Hebron Family Practice in Hebron and a senior-attending physician at Middlesex Hospital. She served as president of the Connecticut Academy of Family Physicians from 1991 to 1992 and as president of the Middlesex County Medical Association from 1993 to 1994. Dr. McShane was a member of the Middlesex County Medical Association, where she served as a delegate to the Connecticut State Medical Society, and the Connecticut State Medical Society. Dr. McShane died 21 October 1998 at the age of 48.

SCHOLHAMER, CHARLES F., SR., Yale University School of Medicine, 1942. Dr. Scholhamer was a pediatrician in New Haven for 25 years. Prior to his retirement, he was assistant medical director for Aetna Life and Casualty, Inc. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society where he served on the advisory committee on maternal and child health during the 1970s. Dr. Scholhamer died 2 October 1998 at the age of 81.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a *free* service to the medical profession, hospitals, and communities in Connecticut.

***Opportunities* should be typed, double-spaced copy on letterhead and submitted to CSMS, Physician Placement Service, 160 St. Ronan Street, New Haven, CT 06511 (203) 865-0587 or fax to (203) 865-4997. These will be published as space permits and will be distributed to physicians inquiring about such *opportunities*.**

***Physicians wishing to locate* in Connecticut may call the office requesting opportunities in their specialty. Also, candidates are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.**

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

Announcements on the Physician Placement Service page under Classified Advertising are charged at the regular Classified Advertising rate.

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Full-time M.D. needed for ambulatory out-patient facility in Fairfield. No weekends, hospital rounds or late nights. Fax CV to (203) 366-7566, attention Dr. Luecken.

INTERNAL MEDICINE

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Connecticut Medicine

Journal of the Connecticut State Medical Society

TITLE INDEX

Volume 62 December 1998

A

A Community Hospital's Ambulatory Addiction Medicine Program (Kraus, Ziedonis, Feinberg, Segal, Israel, Kraus) .... (Feb) 89

A Case Report: Extralobar Pulmonary Sequestration in a Newborn (Kellett, Neumann, Scholl) .... (Jan) 15

A Cluster of Cases of Subacute and Silent Thyroiditis in the Greater Hartford Area (Dulipsingh, Ikram, Malchoff, Shoukri) .... (Jul) 395

Acute Transverse Myelitis in Systemic Lupus Erythematosus: A Case of Rapid Diagnosis and Complete Recovery (Habr, Wu) .... (Jul) 387

Address for White Coat Ceremony: New York Medical College Convocation (Robin) .... (Mar) 171

A Rare Manifestation of Parathyroid Carcinoma Presenting as a Cystic Neck Mass (Pirundini, Zarif, Wihbey) .... (Apr) 195

As Life Ebbs, So Does Time to Elect Comforts of Hospice (Stolberg) .... (May) 287

A Special Report on the National Congress on the Future of Medical Practice and Practice Management (Reece) .... (Dec) 721

Author Index .... (Dec) 766

Abstracts

Abstract of Papers: Danbury Hospital, 13th Annual Joseph L. Belsky, M.D., Research Day, 13 May 1998 (Danbury Hospital) .... (Aug) 465

B

Book Reviews .... (Apr) 251,(Aug) 509, (Oct) 636, (Nov) 695, (Dec) 756

C

Case Report: An Autopsy Study of a Rae T-cell Lymphoma Clinically Misdiagnosed as Fulminant Hepatic Disease (Schwartz, Rezuke, Cartun, Hasson) .... (Nov) 643

Childhood Injury in Connecticut (Lapidus, Lerer, Zavoski, Banco) .... (Jun) 323

Cigarette Smoking in Connecticut: Home and Workplace Exposure (King, Strouse, Hovey, Zehe) .... (Sep) 531

Clinical Evaluation of Hand-Arm-Vibration Syndrome in Shipyard Workers: Sensitivity and Specificity as Compared to Stockholm Classification and Vibrometry Testing (Kent, Allen, Bureau, Cherniack, Hans, Robinson) .... (Feb) 75

Connecticut State Special Olympics: Observations and Recommendations (Galena, Epstein, Lourie) .... (Jan) 33

Commentary

"A Close Look at Therapeutic Touch" (Almond) .... (Jun) 353

Back to the Bedside (Goodwin) .... (May) 295

COURAGE—An Epistle to a Colleague (Katz) .... (Jul) 429

Further Thougths on a Sustainable Medicine (Vietzke) .... (Dec) 731

Hold the Mayo (Aronson) .... (Aug) 491

Journal (Stack) .... (Nov) 679

Malpractice Coverage in Connecticut for the Last 30 Years (Redmond) .... (May) 296

Physician Liability for Suicide of Noncustodial Patients (Newman) .... (May) 297

Science and Sense (Needham) .... (May) 295

Survey of the Retired Fairfield County Physicians (FCMA) .... (Nov) 680

The Corporatization of the United States Health-Care System (Relman) .... (Feb) 97

The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America (Katz) .... (Oct) 619

The Need for Single-Payer Catastrophic Health Insurance (Bentivegna) .... (Apr) 235

The Primary Care Physician and Managed Care (Mangi) .... (Oct) 615

Why Congress Must Regulate Managed Care (Norbeck) .... (Aug) 492

CPRO Corner

CPRO Focus Now on Quality Improvement Collaboration (Roberts) .... (May) 309, (Sep) 561

CSMS

Address of the Executive Director .... (Jun) 375, (Oct) 689, (Dec) 753

Address of the Retiring President .... (Jun) 379

Annual Meeting of the House of Delegates .... (Jun) 368

Call .... (Mar) 187, (Apr) 247, (Sep) 565

Committee Service Questionnaire .... (Nov) 699, (Dec) 752

Connecticut State Medical Society Conflict of Interest Policy .... (Oct) 633

Consumer Concern or Complaint Form .... (Nov)

Council Minutes .... (May) 315, (Aug) 505, (Oct) 630, (Dec) 745

Semi-Annual Meeting of the House of Delegates .... (Dec) 749
CSMS Physician Placement Service
(CSMS) .... (Jan) 57, (Feb) 121, (Mar) 190,
(Apr) 254, (May) 318, (Jun) 383, (Jul) 445,
(Aug) 510, (Sep) 569, (Oct) 637,
(Nov) 701, (Dec) 759
Report to the Semi-Annual Meeting
of the CSMS House of Delegates
(Czarsty) .... (Dec) 737

D

Do Physicians Discuss Genetic Testing with
Family-History-Positive Breast Cancer Patients?
(Polednak) .... (Jan) 3
Drug Information Update: Hartford Hospital
Antimicrobial Switch Therapy
(Bui, Quintiliani) .... (Nov) 665
Antiretroviral Therapy: An Update
(Reddy, Ross) .... (Jan) 25
Atorvastatin (Lipitor®)
(Tucker) .... (May) 283
Formulary Review of the Carbapenems:
Comparison of Imipenem/Cilastatin and Meropenem
(Richerson, Ambrose, Quintiliani, Nightingale) .... (Mar) 165
Remifentanil (Ultiva™)
(Milch-White) .... (Feb) 85
Sildenafil: A New Therapy for Erectile Dysfunction
(Dunn) .... (Jul) 413
Trovafloxacin: Fourth Generation Fluoroquinolone
(McNabb, Nicolau, Quintiliani, Nightingale) .... (Aug) 483

E

Editorials, Guest
Assistance with Suicide
(Coll) .... (Mar) 174
"Slow Down, You Move Too Fast"
(Sachs) .... (Feb) 96
The Role of the Primary Pediatrician When a Child Dies
(Wessel) .... (Nov) 677
Why Not to Invest in a Publicly Traded Managed Care System
(Gray) .... (Feb) 95
Widespred HIV Antibody Testing of Pregnant Women—How
Accurate?
(Melchreit) .... (Oct) 621

Epitomes of Progress
Important Advances in Clinical Medicine:
Allergy and Immunology .... (Apr) 226
Dermatology
(Matarasso) .... (Nov) 619
Family and General Practice
(Sonander, Rai) .... (Jan) 19
General Surgery
(Wilson) .... (Mar) 155
Internal Medicine
(Feinstein) .... (Jul) 399
Neurology
(Thal) .... (May) 267
Psychiatry
(Rosenfeld) .... (Aug) 475
Urology
(Nachtsheim) .... (Sep) 541, (Oct) 589

F

Factors Inhibiting Use of the Pneumococcal Polysaccharide Vaccine:
A Survey of Connecticut Physicians
(Metersky, Mennone, Fine) .... (Nov) 649
Frequency of Breast Biopsy and Breast Cancer Diagnosis in Central
Connecticut—Trends From 1993 to 1997
Ricci, Banever) .... (Mar) 143
Fifty Years Ago
Actuarial Society Analyses Surgical Benefit Claims .... (Sep) 553
An "Index of Curative Skill" .... (Aug) 495
Dr. Blumer Honored .... (Dec) 736
Drs. Fulton and Winternitz Receive Awards .... (Dec) 736
Dr. Gesell Heads Child Vision Research Project .... (Dec) 735
Dr. Senn New Head of Yale Child Clinic .... (Dec) 735
Editorial: A Corporate Society .... (Jul) 434
Experience is the Best Teacher .... (Jun) 355
Fifth Memorial Gift to Building Fund .... (Jan) 43
First International Poliomyelitis Conference .... (Sept) 553
Medical Care and the Cost of Living .... (Jul) 433
Medical Practice Group .... (Mar) 175
Medicine in a Planned Economy .... (May) 301
Personality and Practice .... (Feb) 99
The Candidates Speak .... (Oct) 623
The Hartford Hospital Medical Center .... (Apr) 239
Vagitus Tuerinus
(Berlowe) .... (Jul) 434
World Medical Association Second Annual Assembly,
Geneva, Switzerland
(Barker) .... (Nov) 681
From the Executive Director's Office
Address of the Executive Director .... (Jun) 375, (Dec) 753
Address of the Retiring President .... (Jun) 379
Annual Meeting of the House of Delegates .... (Jun) 368
Call .... (Mar) 187, (Apr) 247, (Sep) 565
Committee Service Questionnaire .... (Nov) 699, (Dec) 752
Connecticut State Medical Society
Conflict of Interest Policy .... (Oct) 633
Council Meeting .... (Feb) 111, (May) 315,
(Aug) 505, (Oct) 630, (Dec) 745
Semi-Annual Meeting of the House of Delegates .... (Dec) 749

G

Group B Streptococcal Bacteremia in Adults at Hartford Hospital
1991–1996
(Cooper, Morganelli) .... (Sep) 515

H

Hepatopulmonary Syndrome: A Case Report and Literature Update
(Christy, Atlas) .... (Jul) 391
HIV-Associated Autoimmune Hemolytic Anemia Complicated by
Pulmonary Embolism Following a Red Blood Cell Transfusion:
Case Report and Review of the Literature
(Saif, Morse, Greenberg) .... (Feb) 67
Human Immunodeficiency Virus-Related Progressive Multifocal
Leukoencephalopathy with a CD4$^+$ of 444mm^3: A Case Report
(Lee, Wu, Brett-Smith, Fielder) .... (Oct) 579

I

Impediments in Treatment of Schizophrenic Patients
(Fleck) .... (Dec) 707

Intracranial Subependymoma
(Neumann, Martinez) .... (Oct) 583

Intrinsic Hemangiomas of the Peripheral Nerves
Report of a Case and Review of the Literature
(Ergin, Druckmiller, Cohen) .... (Apr) 209

Is Telemedicine Justifiable?
(Falsone, Moidu, Sheehan, Gottlieb, Galusha, Nair) ...... (Jul) 423

In Memoriam .... (Jan) 55, (Mar) 188,
(Apr) 249, (Jun) 381, (Sep) 567, (Dec) 758

J

James Bryan Herrick: A Man of Intellectual Muscle
(Ramanan) .... (Oct) 601

L

Learning from Mental Illness, Past and Present
(Solnit, Jacobs) .... (Dec) 715

Letters to the Editor

"All Politics Is Local"
(Katz) .... (Jun) 366

Anonymous Poem "My Daddy, M.D."
(Koenig) .... (Sep) 563

Be Not Afraid!
(Katz) .... (Aug) 504

Burdensome Medicare Guidelines
(Volpintesta) .... (May) 312

Cancer Gene Testing?
(Pilarski, Greenstein) .... (Apr) 246

Dr. Chotkowski Responds to Dr. Merrick
(Chotkowski) .... (Jan) 52

Dr. Katz Responds
(Katz) .... (Dec) 741

Drs. Zahir and Dudrick Respond to Dr. Polednak
(Zahir, Dudrick) .... (May) 311

HMOs: Managed-Access, Not Care
(Czarsty) .... (Nov) 692

In Defense of Linguistic Correctness
(Altshul) .... (Jul) 441

In Response to Connecticut College of Emergency Physicians' Abstract by Drs. Daly and Reiser
(Keggi) .... (Mar) 183

In Response to Dr. Bentivegna's Commentary *The Need for Single-Payer Castrophic Health Insurance*
(Needham) .... (Jun) 366

In Response to Dr. Chotkowski's Letter
(Merrick) .... (Jan) 51

In Response to Dr. Dowaliby's Letter
(Welch) .... (Nov) 693

In Response to Dr. Katz's Commentaries
(Spencer) .... (Dec) 743

In Response to Dr. Koenig's Letter to the Editor "My Daddy, M.D."
(Sataline) .... (Nov) 692

In Response to Dr. Lenaz's Letter "Ethics in Managed Care"
(Katz) .... (Jan) 50

In Response to Dr. Maria Lenaz's *Letter to the Editor* "Ethics in Managed Care"
(Merikangs, George, Needham) .... (Feb) 108

In Response to Dr. Marshall's Letter
(Blansfield) .... (Nov) 691

In Response to Dr. Richard Evans's *Update on Childhood Asthma*
(Randolph) .... (Feb) 109

In Response to "Outbreak of Staphylococcal Food Poisoning Associated with Precooked Ham—Florida, 1997"
(Yesner) .... (Mar) 183

In Response to "Pain Control Following Elective Gastrointestinal Surgery: Is Epidural Anesthesia Warranted?"
(Dowaliby) .... (Nov) 693

In Response to *Physician Assisted Living (PAL)*
(Blansfield) .... (Feb) 106

In Response to "The Dream That Never Was: The Rise and Fall of Socialized Medicine in the United States of America"
(Slater) .... (Dec) 741

In Response to "The Ethics of Organ Transplantation"
(Marshall, Jr.) .... (Nov) 691

In Response to the *Physician Assisted Living: The PAL Partner Initiative* Article
(Wessel) .... (Feb) 107

In Response to *Thiamine Deficiency* Article
(Sinatra) .... (Jan) 50

Is There a Place for Hospitalists in Health-Care Reform?
(Volpintesta) .... (Mar) 185

Leg Edema Secondary to Bladder Distention
(Chowdhury, Atlas) .... (May) 313

Literary Gaffes
(Kirchner) .... (Jul) 422

Need for Solidarity
(Volpintesta) .... (Dec) 742

"Neutrinos, the Mind and the Theory of Everything"
(White) .... (Aug) 503

"Physician Assisted Living"
(Schoen) .... (Aug) 503

Professional Vacuum
(Blaney) .... (Mar) 184

Quality-of-Life and end-of-Life Decisions
(Volpintesta) .... (Jul) 441

Regarding: "Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Reveiw of the Connecticut State Tumor Registry"
(Polednak) .... (May) 311

Remembering Wilder Penfield
(Needham) .... (Mar) 184

Round Table Discussion
(Heiger) .... (Jan) 50

Shortfall of Physicians?
(Merikangas) .... (Jul) 422

Should the City Medical Societies Take an Active Part?
(Volpintesta) .... (Feb) 106

Simple Truths
(Needham) .... (Nov) 692

So What About Character?
(Needham) .... (Apr) 246

Thanks
(Wessel) .... (Sep) 563

The Misnomer "Physician Assisted Living"
(Kotch) .... (Mar) 185

The Ethics of Organ Transplantation
(Blansfield) .... (Jun) 367

"Welcome to the World of Managed-Care" Submitted to the *Danbury News-Times*
(Gorelick) .... (Nov) 693

M

Magnetic Resonance Imaging of a Mediastinal Ependymoma
(Neumann, Scholl, Kellet, Simon) .... (Sep) 527

Mental Retardation and Decision Making: Balancing Autonomy and Protection
(Van Hoof, Taggart) .... (Aug) 455

Monitoring Clinical Quality in Medicaid Managed Care
(Bradley, Horwitz, Grogan, Roberto) .... (Apr) 215

Medical Letter, The

Advice for Travelers ....(May) 279

A New Rabies Vaccine .... (Jul) 421

Fenofibrate for Hypertriglyceridemia .... (Aug) 489

Flu Vaccination Decreases Relative Morbidity
Risk for People with Diabetes
(Vinicor) .... (Nov) 676

New "Triptans" and Other Durgs for Migraine .... (Nov) 673

St. John's Wort ....(Jan) 31

Toremifene and Letrozole for Advanced Breast Cancer ...... (Jun) 347

Vitamin Supplements .... (Sep) 551

Morbidity and Mortality Weekly Report

Assessing Adolescent Pregnancy—Maine, 1980–1996 .... (Jul) 417

Changes in Mortality From Heart FAilure—
United States, 1980–1995 .... (Oct) 595

Civilian Outbreak of Adenovirus Acute Respiratory
Disease—South Dakota, 1997 .... (Sep) 547

Mortality Among Children with Sickle Cell Disease
Identified by Newborn Screening During 1990–1994—
California, Illinois, and New York .... (Jun) 343

Outbreak of Staphylococcal Food Poisoning, Associated with
Precooked Ham—Florida, 1997 ....(Jan) 29

Update: Syringe Exchange Programs—
United States, 1997 .... (Nov) 669

N

Neuromuscular Oropharyngeal Dysphagia Secondary to Bone Metastases
(Shames, Sheinbaum) .... (Aug) 451

Noxious Fumes in a Medical Center:
Chemical and Psychological Aspects
(York, Hodgson, Cooper, McKay, Jr.) .... (Feb) 71

O

Obiturary—Robert R. McDonnell
(Brunell) ....(Jan) 53

'On Machine': His Doctors Avoided the
Dying Patient's Agongy
(D'Honau) .... (Jun) 349

Ongoing Physician Guidance to Achieve Periodic Mammography of
Women at an Urban Health Center
Gregorio, Nestler, Gould, Paturzo) .... (Apr) 221

P

Pain Control Following Elective Gastrointestinal Surgery: Is
Epidural Anesthesia Warranted?
(Welch, Cohen, Vignati, Allen, Morrow, Carter) .... (Aug) 461

Pleural Fluid: Accuracy of Computed Tomography
in Differintiating Exudates from Transudates
(Wolek, Mason, Reeser, Ains) ....(May) 259

Predischarge Outcomes of 22–27 Weeks Gestational Age
Infants Born at Tertiary Care centers in Connecticut:
Implications for Perinatal Management
(Hussain, Galal, Ehrenkranz, Herson, Rowe) .... (Mar) 131

Primary Health-Care Physicians:
Vital Roles in Organ and Tissue Donation
(Coolican, Swanson) .... (Mar) 149

Principles of Cooperation in Medical-Legal Matters
(Walzer) .... (Oct) 605

President's Page, The

An Alternative from the Midwest
(Keating, Jr.) .... (Feb) 101

Breaking Down the Walls of Cynicism?
(Czarsty) .... (Aug) 497

COMPAC Revisited and a New Editor for *Connecticut Medicine*
(Czarsty) .... (Sep) 555

Engaged in the Dialogue
(Keating, Jr.) .... (Apr) 241

Evaluation and Management Coding
(Keating, Jr.) .... (Mar) 177

In Memoriam: Kathleen McShane, M.D., 1950–1998
(Czarsty) .... (Nov) 685

Memorial Day
(Keating, Jr.) ....(May) 303

Preaching to the Choir
(Keating) ....(Jan) 45

Report to the Semi-Annual Meeting
of the CSMS House of Delegates
(Czarsty) ....(Dec) 743

Rising Health-Care Costs and Physician Unity
(Czarsty .... (Oct) 625

The Challenge of Change
(Czarsty) .... (Jun) 359

What Is Your Excuse?
(Czarsty) .... (Jul) 435

R

Rapid Multiplex Analysis for the Factor V Leiden and Prothrombin
G20210A Mutations Associated with Hereditary Thombophilia
(Linfert, Rezuke, Tsongalis) .... (Sep) 519

Report to the Semi-Annual Meeting
of the CSMS House of Delegates
(Czarsty) ....(Dec) 743

Research Promotion Between Managed Care Organizations
and Healthcare Delivery Systems
(Lenaz) ....(Jan) 39

Reflections on Medicine

A Question of Virtue
(Massey) .... (Sep) 557

A Sustainable Medicine
(Massey) .... (Jul) 437

Hermann Helmholtz: From Army Surgeon to Physicist
(Massey) .... (Mar) 179

More on Sustainable Medicine
(Massey) .... (Aug) 499

Neutrinos, the Mind, and the Theory of Everything
(Massey) .... (Jun) 363

On Words, Style, Grammar, and Other Matters
(Massey) ....(May) 305

Signs of the Times?
(Massey) .... (Oct) 627

Suicide Is a Private Affair
(Massey) ....(Dec) 739

The Kinsey Report: After 50 Years, Bogus Science
(Massey) .... (Jan) 47
Tragic Fall or Angle of Repose?
(Massey) .... (Apr) 243
Twilight of the Heroes?
(Massey) .... (Nov) 687
What About Character?
(Massey) .... (Feb) 103

S

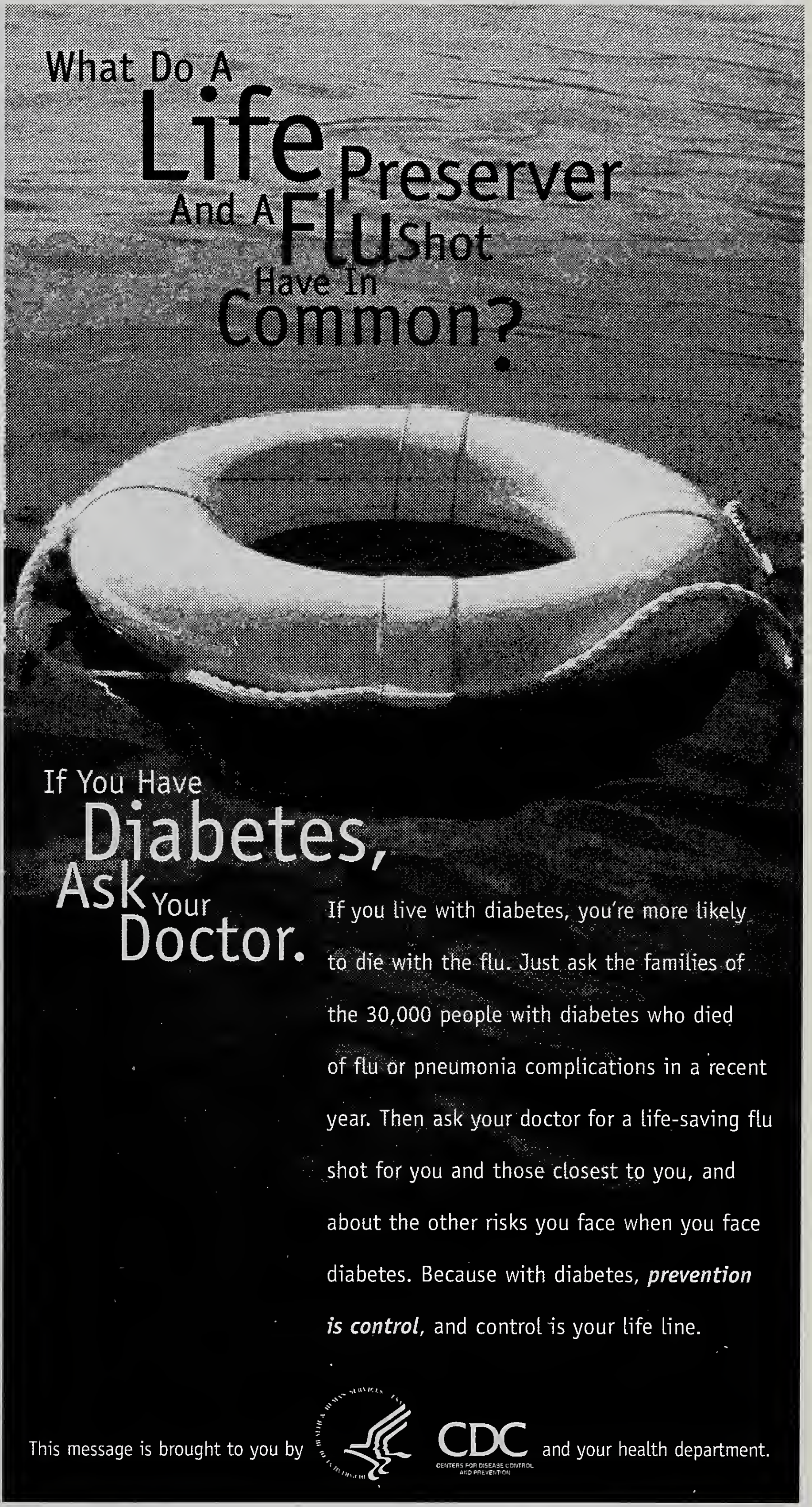
Significance of Coagulase-Negative Staphylococci in Urinary Tract Infections in a Developing Country
(Orrett, Shurland) .... (Apr) 199
St. John's Wort
(The Medical Letter) .... (Jan) 31
Systemic Cat Scratch Disease: A Brief Case Report and Review of the Literature
(Rosenberg) .... (Apr) 205

T

Teaching Care of Terminally Ill Patients: A Primary Care Perspective
(Angoff, Goldie) .... (Mar) 139
Teaching Senior Medical Students in an Office Setting: The Apprentice System Revisited: A Cardiologist's Perspective
(Phinney Jr., Hager) .... (Jun) 337
The AMA's Evaluation and Management Coding Conference of 27 April 1998
(Levinson) .... (May) 291
Title Index .... (Dec) 761
Trends in the Incidence of Upper Extremity Soft Tissue Malignancies: A 40-Year Review of the Connecticut State Tumor Registry
(Zahir, Quin, Brown, Thomson, Dudrick) ...... (Jan) 9
Thrombotic Thrombocytopenic Purpura Following Influenza Vaccination—A Brief Case Report
(Ramakrishnan, Parker) .... (Oct) 587
Two Lives, Interlaced, End One day Apart
(Yoon) .... (Jan) 41
This Month's Reading in Review
(Norbeck) (Jan) 49, (Feb) 105, (Mar) 181, (Apr) 245, (May) 307, (Jun) 365, (Jul) 439, (Aug) 501, (Sep) 559, (Oct) 629, (Nov) 689, (Dec) 740

W

Workplace Violence: Occupational Safety and Health Administration Guidelines for Workers in Health Care and Social Services
(Trapé) .... (Jun) 333


What Do A Life Preserver And A Flu Shot Have In Common?
If You Have Diabetes, Ask Your Doctor.
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

If you live with diabetes, you're more likely to die with the flu. Just ask the families of the 30,000 people with diabetes who died of flu or pneumonia complications in a recent year. Then ask your doctor for a life-saving flu shot for you and those closest to you, and about the other risks you face when you face diabetes. Because with diabetes, ***prevention is control***, and control is your life line.

This message is brought to you by CDC and your health department.

AUTHOR INDEX

Volume 62 **December 1997**

A

Allen, LW (Aug) 461
Allen, R (Feb) 75
Almond, AM (Jun) 353
Ambrose, PG (Mar) 165
Atlshul, VA (Jul) 441
Angoff, NR (Mar) 139
Aronson, SM (Aug) 491
Atlas, S (May) 313, (Jul) 391

B

Banever, T (Mar) 143
Banco, L (Jun) 323
Barker, C (Nov) 681
Bentivegna, JF (Apr) 235
Berlowe, ML (Jul) 434
Blaney, L (Mar) 184
Blansfield, HN (Feb) 106, (Jun) 367, (Nov) 691
Bradley, EH (Apr) 215
Brett-Smith, H (Oct) 579
Brown, W (Jan) 9
Brunell, RJ (Jan) 53
Bui, K (Nov) 665
Bureau, P (Feb) 75

C

Carter, JJ (Aug) 461
Cartun, RW (Nov) 643
Cherniack, M (Feb) 75
Chotkowski, LA (Jan) 52
Chowdhury, S (May) 313
Christy, E (Jul) 391
Cohen, JL (Aug) 461
Cohen, P (Apr) 209
Coll, PP (Mar) 174
Coolican, MB (Mar) 149
Cooper, BW (Feb) 71, (Sep) 515
Czarsty, CW (Jun) 359, (Jul) 435, (Aug) 497, (Sep) 555, (Oct) 625, (Nov) 685,692, (Dec) 737

D

D'Honau, MM (Jun) 349
Dowaliby, JM (Nov) 693
Druckmiller, WH (Apr) 209
Dudrick, SJ (Jan) 9, (May) 311
Dulipsingh, L (Jul) 395
Dunn, A (Jul) 413

E

Ehrenkranz, RA (Mar) 131
Epstein, CR (Jan) 33
Ergin, MT (Apr) 209

F

Falsone, JJ (Jul) 423
Feinstein, DI (Jul) 399
Feinberg, MA (Feb) 89
Fiedler, P (Oct) 579
Fine, JM (Nov) 649
Fleck, S (Dec) 707

G

Galal, M (Mar) 131
Galena, HJ (Jan) 33
Galusha, L (Jul) 423
George, RC (Feb) 108
Goldie, SJ (Mar) 139
Goodwin, RA (May) 295
Gorelick, JI (Nov) 693
Gottlieb, K (Jul) 423
Gould, B (Apr) 221
Gray, FS (Feb) 95
Greenberg, BR (Feb) 67
Greenstein, RM (Apr) 246
Gregorio, DI (Apr) 221
Grogan, CM (Apr) 215

H

Habr, F (Jul) 387
Hager, WD (Jun) 337
Hans, J (Feb) 75
Hasson, J (Nov) 643
Heiger, AA (Jan) 50
Herson, VC (Mar) 131
Hodgson, MJ (Feb) 71
Horwitz, SM (Apr) 215
Hovey, DA (Sep) 531
Hussain, N (Mar) 131

I

Ikram, Z (Jul) 395
Israel, L (Feb) 89

J

Jacobs, WW (Dec) 715

K

Katz, SR ... (Jan) 50, (Jun) 366, (Jul) 429, (Aug) 504, (Oct) 619, (Dec) 741
Keating, SJ. Jr. ... (Jan) 45, (Feb) 101, (Mar) 177, (Apr) 241, (May) 303
Keggi, JM ... (Mar) 183
Kellett, HM ... (Jan) 15, (Sep) 527
Kent, DC ... (Feb) 75
King, G ... (Sep) 531
Kirchner, JA ... (Jul) 422
Koenig, AR ... (Sep) 563
Kotch, PI ... (Mar) 185
Kraus, MC ... (Feb) 89
Kraus, ML ... (Feb) 89

L

Lapidus, G ... (Jun) 323
Lee, L ... (Oct) 579
Lenaz, M ... (Jan) 39
Lerer, T ... (Jun) 323
Levinson, SR ... (May) 291
Linfert, DR ... (Sep) 519
Lourie, RJ ... (Jan) 33

M

Malchoff, CD ... (Jul) 395
Mangi, RJ ... (Oct) 615
Marshall Jr., J ... (Nov) 691
Martinez,H ... (Oct) 583
Mason, BJ ... (May) 259
Massey, RU ... (Jan) 47, (Feb) 103, (Mar) 179, (Apr) 243, (May) 305, (Jun) 363, (Jul) 437, (Aug) 499, (Sep) 557, (Oct) 627, (Nov) 687, (Dec) 739
Matarasso, SL ... (Nov) 619
Metersky, ML ... (Nov) 649
McKay, CA, Jr. ... (Feb) 71
McNabb, J ... (Aug) 483
Melchreit, R ... (Oct) 621
Mennone, JZ ... (Nov) 649
Merikangas, JR ... (Feb) 108, (Jul) 422
Merrick, TC ... (Jan) 51
Milch-White, L ... (Feb) 85
Moidu, K ... (Jul) 423
Morganelli, E ... (Sep) 515
Morrow, JS ... (Aug) 461
Morse, EE ... (Feb) 67

N

Nachtsheim, DA ... (Sep) 541, (Oct) 589
Nair, S ... (Jul) 423
Needham, CW ... (Feb) 108, (Mar) 184, (Apr) 246, (May) 295, (Jun) 366, (Nov) 692
Nestler, EO ... (Apr) 221
Neumann, DP ... (Jan) 15, (Sep) 527, (Oct) 583
Newman, RL ... (May) 297
Nicolau, D ... (Aug) 483
Nightingale, CH ... (Mar) 165, (Aug) 483
Norbeck, TB ... (Jan) 49, (Feb) 105, (Mar) 181, (Apr) 245, (May) 307, (Jun) 365, (Jul) 439, (Aug) 492,501, (Sep) 559, (Oct) 629, (Nov) 689, (Dec) 745,753

O

Orrett, FA ... (Apr) 199

P

Parker, LP ... (Oct) 587
Paturzo, D ... (Apr) 221
Pilarski, R ... (Apr) 246
Phinney, Jr., AO ... (Jun) 337
Pirundini, P ... (Apr) 195
Polednak, AP ... (Jan) 3, (May) 311

Q

Quin, JA ... (Jan) 9
Quintiliani, R ... (Mar) 165, (Aug) 483, (Nov) 665

R

Rai, DS ... (Jan) 19
Ramakrishnan, N ... (Oct) 587
Ramanan, SV ... (Oct) 601
Randolph, C ... (Feb) 109
Reddy, P ... (Jan) 25
Redmond, AP ... (May) 296
Relman, AS ... (Feb) 97
Reece, RL ... (Dec) 721
Reeser, P ... (May) 259
Rezuke, WN ... (Sep) 519, (Nov) 643
Ricci, Jr., A ... (Mar) 143
Richerson, MA ... (Mar) 165
Roberto, M ... (Apr) 215
Roberts, K ... (May) 309
Robin, NI ... (Mar) 171
Robinson, M ... (Feb) 75
Rosenberg, R ... (Apr) 205
Rosenfeld, II ... (Aug) 475
Ross, J ... (Jan) 25
Rowe, JC ... (Mar) 131

S

Sachs, FL ... (Feb) 96
Saif, MW ... (Feb) 67
Sataline, L ... (Nov) 692
Schoen, EK ... (Aug) 503
Scholl, RJ ... (Jan) 15, (Sep) 527
Schwartz, RA ... (Nov) 643
Segal, SR ... (Feb) 89
Shames, D ... (Aug) 451
Sheehan, CA ... (Jul) 423
Sheinbaum, R ... (Aug) 451
Shoukri, KC ... (Jul) 395
Shurland, SM ... (Apr) 199
Simon, RH ... (Sep) 527
Sinatra, ST ... (Jan) 50
Slater, GS ... (Dec) 741

Spencer, S ... (Dec) 743
Solnit, AJ ... (Dec) 715
Sonander, JO ... (Jan) 19
Stack, MND ... (Nov) 679
Stolberg, SG ... (May) 287
Strouse, R ... (Sep) 531
Swanson, MA ... (Mar) 149

T

Taggart, WB ... (Aug) 455
Thomson, JG ... (Jan) 9
Thal, LI ... (May) 267
Tucker, G ... (May) 283
Trapé, M ... (Jun) 333
Tsongalis, GJ ... (Sep) 519

V

Van Hoof, TJ ... (Aug) 455
Vietzke, WM ... (Dec) 731
Vignati, PV ... (Aug) 461
Vinicor, F ... (Nov) 676
Volpintesta, EJ ... (Feb) 106, (Mar) 185, (May) 312, (Jul) 441, (Dec) 742

W

Walzer, RS ... (Oct) 605
Welch, JP ... (Aug) 461, (Nov) 693
Wessel, MA ... (Feb) 107, (Sep) 563, (Nov) 677
Wihbey, JG ... (Apr) 195
Wilson, SE ... (Mar) 155
White, F ... (Aug) 503
Wolek, R ... (May) 259
Wu, B ... (Jul) 387, (Oct) 579

Y

Yesner, R ... (Mar) 183
Yoon, H ... (Jan) 41
York, E ... (Feb) 71

Z

Zahir, KS ... (Jan) 9, (May) 311
Zarif, A ... (Apr) 195
Zavoski, R ... (Jun) 323
Zehe, L ... (Sep) 531
Ziedonis, D ... (Feb) 89
Zins, JH ... (May) 259

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